Discussion of Coverage and Reimbursement Report
October 19, 2004

MS. BERRY: Everyone should have the handout that was distributed this morning. The front page goes over what we at least temporarily tentatively decided in terms of recommendations with regard to the screening exclusion and the national versus local coverage decisions. I won't go over those again, but take a look. The reverse side addresses genetic counseling. We started that, but didn't wrap it up.

We went back with staff and came up with a revised set of potential recommendations, and wanted to start this morning going over that. The first recommendation talks about the analysis that we discussed. We didn't specify who would do the analysis. The analysis could be simply reliance on what HRSA is already doing. If not, it could be the Institute of Medicine. We are in the process of trying to determine the state of play of the HRSA effort, and determining whether an additional analysis is needed. So we have purposely left that vague.

The idea is that someone needs to do a comprehensive look at who is qualified to provide genetic counseling services, under what conditions, who should be supervised, who doesn't need supervision, and how should they be reimbursed. It should also look into the effectiveness and value of providing these services.

If there are any gaps in that analysis that are uncovered, that could lead to a Medicare demonstration project which would provide us with additional data that would help address some of the questions and barriers outlined in the report on genetic counseling access. The third proposed recommendation has to do with a legislative change.

If the data analysis and the data gleaned from the demonstration project indicate and support this, and we all think it will, then perhaps we would be in a position to advocate a legislative change, a congressional fix where we would add all of the appropriate health care providers to the list of non-physician providers who can directly bill Medicare.

We purposely left that open, not really wanting to limit it to one specialty or another, because there are many different health care providers who are able and capable of providing these types of services. So the analysis and demonstration project, if we have one, will help inform who those people should be.

The fourth potential recommendation addresses the issue of licensure. Licensure of genetic counselors in particular. We have a question mark there, because the feeling was that we'd probably need a little bit more discussion on that. Is this something that this committee should promote? Do we have any authority, or does the Secretary have any ability to influence states in whether they set up some sort of licensure process for different health care providers such as genetic counselors? That's a question mark in my mind, and I'd welcome further discussion. I wish Barbara were here, because I know she'd have some input on that as well.

DR. McCABE: I think it's certainly a critical piece, because without licensure, it is going to be difficult to bill. I think you are also correct that it is going to be hard for us to have an impact, because this is a state by state issue.

It can certainly be built into the logic of the argument that it is a critical piece. I think we should try and recommend things that are doable, even if they are a bit of a reach. I think this one is probably not really doable, but should certainly be commented upon in the logic of the argument.

MS. BERRY: Do you think, Ed, just to follow up, that perhaps the issue would be addressed in the meat of the report, but not constitute a recommendation? Or do you have a thought for how we could phrase a recommendation that would address this?

DR. McCABE: I think it should be definitely in the meat of the report. It could be under Number 1, because that addresses, if we look at the first bit, an analysis that will determine which health providers are qualified to provide genetic counseling, under what conditions, and under what supervision. I think it is the supervision point that if there is licensure, then there is less need for supervision, so that one could build it into that first sentence, perhaps, in a parenthetical.

DR. LEONARD: I know that genetic counselors are very, very valuable today in the services that they provide. They can't bill, and they can't be paid for what they do. These services are underwritten by departments just because it is a necessary part of medical genetics.

I feel like only asking for a study, although maybe necessary is leaving those genetic counselors who are out there practicing still flapping in the wind. I don't know if that is a very effective thing to be doing. If I was a genetic counselor looking at these recommendations, I'd probably be very angry, and feel like I wasn't getting any assistance from this committee, because a study is going to take at least six months to be commissioned, and about a year to 18 months to do. There are people out there currently practicing and adding a lot of value in the medical genetics area.

MS. BERRY: Do you have a specific idea on how you might address that, or some of their concerns? Is licensure where you would put the focus? Or are there other areas that you think we should focus on?

DR. LEONARD: Well, there is licensure coming in two states, so there is a move towards licensure. Maybe we should create a mechanism whereby people that are licensed to provide genetic counseling services can be acknowledged as allied professionals and get a UPIN so that they can bill for the services that they are providing as licensed health care professionals.

DR. WINN-DEEN: So I think we also heard pretty strongly from Barbara yesterday, so I'll just try and represent this again, that there is already a national accreditation program for genetic counselors. I, for one, have a little trouble understanding why a nationally accredited counselor also needs to go through a state licensure, and why that national level of accreditation isn't acceptable per se.

Now, I understand you might have to send the state you live in $50 and get a piece of paper. But I think we also ought to encourage that people who have received that level of national accreditation on the basis of a Master's degree in genetic counseling, that that ought to be sufficient as well.

DR. LEONARD: But it's not in any health care profession. So physicians who have gone to medical school, residency, training, board certification, and everything else, can't practice unless they get a license from the state in which they practice. So this is standard for being able to bill. So I do think you can't get around the licensure. That is going to have to be done on a state by state basis.

If there are states that are licensing, then if we allow those states to bill, maybe it would encourage other states, not those states to bill, but genetic counselors in those states to bill, because they are licensed and can get a UPIN and bill, then maybe there would be other states that would license as well.

DR. KHOURY: I would like to urge the committee not to be a bit myopic in its view. Right now, I think you are just focusing with a real tunnel vision on the specialty of genetic counseling. I mean, if you think about the practice of medicine in the next 10, 20, 30 years, there is going to be the delivery of genetic information not only for the diagnosis and management of genetic diseases which account for 5 percent of

all human disease, but in the management, prevention, and diagnosis for all diseases, whether they are genetic or not.

So if you kind of step back here and you want to provide the maximum value added advice to HHS, then ask the question, how are we going to be ready in delivering genetic information? I'm not saying genetic counseling is not important, because genetic counseling is of paramount importance, at least in a fraction of the delivery of genetic information.

What has happened over the years is that genetic counseling as an institution has really grown up to have a very well defined way of doing business primarily in a non-directive fashion, or the usual way of delivery of genetic services. Whereas the new practice of medicine in the 21st Century is going to be dictating a new paradigm shift in how information is going to be delivered.

For a fraction of cases or people who come through the clinic, the traditional genetic services paradigm will still hold. Increasingly, we are going to be faced with applications from pharmacogenomics, somatic cell genomics, and gene expression arrays for which information is not going to be necessarily delivered through the genetic counseling route.

So, for example, instead of saying an analysis is needed that will determine which health providers are qualified to provide genetic counseling, if you kind of expand your look and you say, of course we're expecting health care providers to provide genetic information in the future, but how do we get there? Under what consensus do we rely on genetic counselors to do that part of the work?

To me, the practice of genetics in the 21st Century is going to be a lot like the practice of infectious diseases, because right now, anybody can order a blood culture. Any health care provider can order a culture and can prescribe antibiotics. So what is the infectious disease specialist? The role of the infectious disease specialist is probably to teach the health care providers, what did I think to do? Maybe in a small subset of complicated or complex cases, to take them on, to be consulted on.

So I would urge the committee to have a more open view of the practice of medicine in asking the genetic counseling questions under the umbrella of delivery of genetic information. Because once you open that door, genetic counseling will have a role in it, but it won't be the only thing that you will focus on.

DR. WILLARD: I can't add much to Muin's typically articulate phrasing of the issue. I had scribbled down many of the same issues in terms of trying to broaden this to genetic and genomic services of which genetic counseling is clearly one avenue, rather than carrying out what I heard Debra say, which is a sense that our remit here is to try to help and rescue one particular subset of the workforce. Although any of us as individuals may bring that to the table, I don't think that that is a particular charge to the committee.

As Muin said, it is a charge to the committee to advise the Secretary on how best to organize the provision of genetic and genomic informational services. To me, licensure issues are way, way down the list. Especially if one tries to create a linkage to billing. Licensure of physicians, they are not getting a license to bill. They are getting a license to practice medicine even if they weren't billing, even if they were doing it for free, they'd still have to have a license.

So there is no direct connection between the act of licensure, and the right to bill. I would sort of pull ourselves up as a committee to the sort of 5,000-foot level of how do we best organize the scene to provide services globally for all the groups that we can imagine might be involved in providing genetic and genomic services, of which board-certified genetic counselors are one, but by no means the only group that will be relevant to that.

DR. McCABE: To move us forward, I have written down some things here, taking the comments and some of my own thoughts. We could relabel this section on genetic services and counseling. We could take the first sentence and say, "SACGHS believes that delivering genetic services, including genetic counseling, is a critically important component."

We could add a sentence at the end of Number 1. I understand Debra's concern about analysis, but I think unfortunately it needs to be deliberate. It may be that these analyses are underway, and therefore, that would speed things up. I would add a sentence at the end of Number 1, "This analysis should address workforce needs, independent practice and licensure of health providers delivering genetic counseling, and other genetic services."

So to try and broaden it out. I know it is not as broad and not as high an altitude level as was recommended, but I think it does broaden it a bit and gives us some specific language.

DR. WINN-DEEN: Well, okay, so I think that we should make sure that if we're going to broaden it beyond genetic counseling, right now this box sits in a section entitled "Genetic Counseling," which I think, Hunt, is why it was limited to genetic counseling.

One thing that I think we haven't captured in this box that we discussed to some extent yesterday was the provision of counseling by other individuals then officially designated genetic counselors, such as oncology nurses, and such as practice nurses who have specialized knowledge of a disease area where they are working. A cystic fibrosis clinic or whatever kind of a disease specialty area.

I think we shouldn't ignore, and I think this is maybe where Hunt was coming from. We shouldn't ignore all these other people that are doing this today, providing counseling services without the official imprimatur of being a genetic counselor. Also the fact that as we move into the genetics of common complex diseases, that this will have to be a much more distributed effort. There is no way we could concentrate it in a single small subspecialty.

DR. McCABE: That's why I broadened it to say genetic services including genetic counseling. I think that would allow one to address the other health providers and evaluate what the roles of these individuals could be.

DR. LEONARD: And I think it was mentioned yesterday also that the nurses who are providing these genetic counseling services are certified. So there is a certification process that says they are qualified to do these things.

DR. WINN-DEEN: I'm not in any way saying that the people who do it shouldn't be qualified. I'm just saying that there are people who are not designated officially as genetic counselors who are doing it. They have received the training, the knowledge, and they are prepared to do it. Some of them are physicians, some of them are nurses, and some of them are probably social workers in some cases.

MS. BERRY: What we tried to do yesterday was to broaden this, because there was some sensitivity about limiting it to one specialty, or one area of practice. But Ed's changes, I think, and with Muin's recommendations, really improve upon that.

Perhaps then to address Emily's point, we beef up the substance of the report, because I don't think there is enough discussion of all of the different specialties. It was initially drafted as a genetic counseling piece.

So as you pointed out, Emily, we need to make the substance fit in with the recommendation, so to speak.

DR. TUCKSON: Could you reread then the last draft that we got from Ed?

DR. TUCKSON: And/or with the Muin modification.

MS. BERRY: The section then would be entitled "Genetic Services and Counseling" or it could be "Delivery of Genetic Services and Counseling." "SACGHS believes that delivering genetic services, including genetic counseling, is a critically important component of the appropriate use and integration of genetic tests and services." We might add in there, "into the practice of medicine, our delivery of health care."

Then the first recommendation is as it appears up there, but adding a sentence. I do actually think we need, because it references only genetic counseling, so we'll need to change that to talk about genetic and genomic services, or some other broader term. Then add a sentence that would read, "This analysis should address workforce needs, independent practice and licensure of health providers delivering genetic counseling, and other genetic services."

So the idea of being where genetic counseling is mentioned specifically, that could be included in a component, but the broader terminology which would be something like "delivery of genetic and genomic services" would be inserted in its place.

DR. TUCKSON: All right. So if I understand it then is that what happens here is that we are saying that this whole field, there are a number of interventions, whether they are counseling and/or procedures and/or other things, that are related to this new field that require clarity around qualifications, scope of practice, so forth and so on. And that that work has to occur, and that we are calling for some order leading us to that.

Then the link is that in absence of that, it is very difficult to recommend reimbursement for those services, given that you don't have this fundamental predicate well enough established or in place. So we are calling attention to the need to be able to create clarity or guidance around reimbursement, but we are making it clear there is a predicate step that has to occur first. Is that essentially what we're doing here?

MS. BERRY: I think you've captured it.

DR. TUCKSON: And then, I guess the second question would be is there any particular reason that we should from that make a special mention of genetic counseling and the reality today for that particular domain. So okay, we have said this now for the whole skrabish.

By the way, right now, given that there are not a lot of interventions to talk about, but right now there is a lot of counseling going on, do we need to, for the sake of the counseling community, sort of say there needs to be some prioritization around moving this along for the counseling community?

DR. McCABE: I think that we actually say genetic counseling, and we put it in small letters rather than in caps. But it is definitely there in several places.

I think what it does is it recognizes those who are doing genetic counseling, which clearly would then be in capital letters, the genetic counselors, the masters, board-certified genetic counselors. But I think also the intent of my amendment was to also address the other individuals who are providing genetic services, including genetic counseling.

DR. TUCKSON: The thesis of my second point is simply to recognize I guess a sort of, and again, I'm just throwing it out there, is the recognition of a certain urgency and prioritization that says look, we've

got to get all this stuff done, but right now we really got this real immediate mess on our hands that we need to have resolved. So we are sort of saying as a first priority, there would be these people that we want to get looked at. I don't know whether philosophically that is where the committee is or not.

DR. FEETHAM: To be consistent with the language we have been talking about about services, framing it as genetic counseling services I think keeps that at that level that we've been now revising this whole thing to look at services. Just in the language of again, not going to individuals, but keeping it at a genetic counseling service. I think that encompasses all of the issues we've been talking about.

DR. LEONARD: I agree with you, Reed, that we do need to address the genetic counseling that is going on now as an urgent issue. I was in no way saying that genetic counselors were going to be providing everything in the future.

But we do know that there is an education gap in the medical workforce. Those who are trained in genetic counseling, be they official genetic counselors, nurses, or whoever, who have gotten the training in genetics will be facilitating the integration of genetics into health care, helping those who don't know genetics to learn that.

Just a clarification. Licensure does not allow you to bill, but without a license, you can't bill. So you do have to have that step before you even have the possibility of billing.

MS. BERRY: Does anyone have any further comment on the three recommendations as revised?

DR. LEONARD: Are we going to add a fourth on the lines of what Reed suggested?

MS. BERRY: Suzanne, have you captured ? -

DR. KHOURY: I have another idea. One of the things that got deleted from yesterday is calling for an IOM analysis of the effectiveness of genetic counseling. This is one of the kind of sticky points right now in the practice of genetics because of the lack of a billable entity related to genetic counseling where people spend a lot of time imparting information that could be useful to people and their families.

I think if we are to call for sort of the big picture recommendation as Number 1 related to the delivery of genetic information and services in general, I think we owe it to the practicing community right now to kind of evaluate in sort of broad terms the ? - I mean, the way you couch it here is effectiveness. Of course people who are practicing this specialty will say, of course it is effective. We are imparting information that would be useful to people.

But when I have had many discussions with a lot of my friends in genetic counseling, what seems to be lacking is a lot of outcome research that could be measurable in a sense to show the clinical utility of that information. I think as a group, I mean, genetic counseling as an entity could benefit from a closer look as to the value and utility of that.

So in other words, if you are to do a randomized clinical trial today, which I don't think anyone will do where you have people coming in and you impart information on with or without genetic counseling, I mean, you can give them a diagnosis and you can send them home, or you can spend an hour or two on genetic counseling. No one is going to do that study for ethical reasons.

But if that study cannot be done, therefore genetic counseling and that hour or two hours should be billable. It has imparted useful information. So it is kind of is a Catch 22 with respect to delivery of current genetic services for single-gene disorders.

I think a closer look as to the utility of that approach is useful. Maybe somebody has done that sometime, but I'm not aware of it.

DR. McCABE: I just wanted to comment.

Muin, you said that it wouldn't be ethically appropriate to do it. Actually, there are some trials ongoing right now with pediatric surgery looking at surgical procedures and clinical trials, which is almost unheard of in surgery to actually look at the efficacy of various surgical procedures. So I think one could design a trial that would be acceptable to IRBs and would answer these questions.

MS. HARRISON: This is Barbara. I think there are also studies that are out there that show different ways to do counseling, whether the counseling is done by a physician versus a trained genetic counselor, and some outcomes from that kind of data. So there are some studies out there that show the efficacy of counseling. I think a literature review effort could unearth some of those.

Otherwise, I just want to make sure, and I think it is getting in there now that I guess my two key issues are licensure to make sure that we put our support behind that being done, as well as I think identifying genetic counseling separately as a key point.

DR. TUCKSON: I was asked to put my thought up there. So what I did was it is actually in Number 1. I don't think it is a separate 4. I think at the very end of Number 1, if we were to say in this next to the last sentence, "This analysis should also address workforce needs, independent practice, and licensure of health providers delivering genetic services. The committee urges that genetic counseling services be a priority for this activity."

I don't know whether that helps or not, but at least you get the whole gamish. Then we come back and say that genetic counseling is a priority.

DR. FEETHAM: As I mentioned yesterday, just a reminder of the study funded by HRSA that was led by Dr. Judith Cooksey is ending at three years. Again, the findings of that may inform. So I just want to remind. I don't have those findings at this point in time, but I just want to remind you that that has been going on, and that may help inform this discussion. You are not starting from a blank slate if you are recommending another study.

DR. TUCKSON: And I didn't get to hear all of Muin's comments. But I think in the sense of the urgency and so forth, I think we need to be clear as a committee in how serious are we about pushing this recommendation forward?

We say we're going to do this study or call for the study, or push forward on this. This is a major, I think, take home issue, and we need to decide if at the end of the day, this is going to be one of the top priorities that comes out of this meeting or not, or whether it is just enough that we put it in our report and send it forward to the Secretary. Or do we really want to come back and consider this to be one of the take homes that define whether our committee was a success or not.

I'm listening for my colleagues to sort of give us a sense of once it is in the report, is this an evaluative issue for our committee.

MS. BERRY: Suzanne, I wondered if I could ask, is the HRSA study limited to allied health professionals? Or is it the whole waterfront? We were talking just a moment ago, does it apply to physicians and geneticists?

DR. FEETHAM: It was looking at genetic specialists, including physicians and non-specialists.

MS. BERRY: Okay. Does the committee have any views on whether we should be focusing on that broadly, is that too broad a focus, or should we hone in a little bit more on the allied health professional world?

Right now it is very broad, and it encompasses, the way it is worded, all specialties, all professions that deliver or potentially could deliver genetic services, including physicians.

MS. CARR: I mean, I was wondering about this as well. I mean, the committee is not interested in asking for an analysis of providers that are now licensed, are we? It is only those who are not currently licensed, or whose license is within a certain scope and may need to be broadened. This wouldn't include M.D. geneticists, would it? It would.

MS. CARR: I know, but I'm wondering if we intended to mean that. What are the issues there that we're trying to get at, I guess?

DR. WILLARD: I mean, I think the issue, and Barbara raised it as well, which health providers are best suited to provide the best genetic or genomic health care? In some cases the answer will obviously be physicians, in other cases it may be genetic counselors, and in some cases it may be nurse practitioners. That's how I read that was sort of a very broad look at the entire landscape of genetic and genomic services, and then saying okay, who is lined up to do the best job under the best circumstances? How is licensure relevant to any of those determinations? That's how I read that.

DR. McCABE: And that's why I thought it is important, again, to be deliberate and analytical, and develop an evidence base. I think there is some literature there, but I think as we move forward, there needs to be a larger literature to really address the workforce needs.

I think buried within that are issues that we've addressed before in this committee. That has to do with education. Are we educating our physicians? In fact, in the management of genetic disease, and I agree with Muin, I think it is going to diffuse throughout all of medicine. But are our medical students being prepared for that medicine?

That's why I think we need to be analytical. I don't think we need to be deliberate for the next two decades. I think we really need to develop the appropriate evidence base to justify the recommendations that many of us would make from our gut in terms of who does what job better.

When Barbara says there is evidence comparing physicians and genetic counselors, that is a no-brainer as a physician, because it is clear that genetic counselors do a far better job in my experience. I think that literature needs to be reviewed, analyzed, and made more public.

DR. WINN-DEEN: So we're working on something that is focused sort of as an overarching subject for this discussion on coverage and reimbursement. So a lot of these issues that we're talking about are more broad, workforce preparedness issues, if you will.

But I think what might be helpful is if staff could put in this a little box chart that just has who are the allied health professionals that are delivering genetic counseling today, and what is their current status? Are they licensed? Who is reimbursable? Who is not? That might make it very clear where we need to focus any further work.

Obviously physicians are already licensed, and they can already bill for their time. So that might not be

where we need to focus services, although some of those physicians might need more education so they can do a better job of doing the counseling. But from a coverage and reimbursement point of view, I think we need to just sort of remember where this section is appearing, in which report, and not get too far off the focus of that issue.

I think we're trying to address the barriers to service provision, and we want to make sure that the people who are actually doing the services can get paid for their work, so that they are inspired to come in and continue to do that every day.

MS. BERRY: Muin, I thought I remembered you expressing some concern about the line where it talks about assessing the effectiveness. Is there a different wording that you propose?

DR. KHOURY: See, what Emily was trying to tell us is to focus a bit on the scope of this section in the report, which is about coverage and reimbursement. If we live in a world where genetic services and genetic counseling is not covered or reimbursed, the question to ask is why.

I mean, if these people, whoever they are, are providing services that are useful to individuals and families, why can't we analyze to see what kind of services we would lose if these services are not provided. If we lose those services, and the health outcomes or psychological outcomes are so much worse off, then why aren't we paying for them?

So it seems to me, and I don't live in this world. I mean, if people say that there is outcomes research out there, let's put it together. This committee can actually recommend that this can be done. We can do it between now and the next meeting and make those recommendations stand better on their feet.

I agree. This is not about the education of the workforce, because that is not in this report. It is about coverage and reimbursement. So given the diffusion of genetics and all of medicine, right now today genetics is concentrated on genetic diseases. So we have to at least solve that part before we begin to diffuse genetics in all of medicine.

I think that the first part, which is single-gene diseases, hasn't really been sold in terms of coverage and reimbursement. So I think this committee can make a very incisive recommendation to at least address and assess these issues.

DR. TUCKSON: Just a subtle addition, and it doesn't change any of the flavor of what Muin said. But I just noticed that we have not said, at least I have not heard that we said explicitly that one of the tasks of this is also to make sure that people don't get ripped off. There is a protection of the public in all of this as well. We focused all of this on what are the good things.

Somebody sets up shop on the corner and says, you know, you've got a genetic disease, I'll talk to you about it. Insurance won't pay for it, but I only charge $30 an hour. It is like H&R Block or something like that. Or telephone hotlines that you know are already there and are springing up.

So we have a telephone hotline thing, and we take credit cards. How does the public know whether these people are any good? So it is part of the reimbursement issue as well. I just want to add that perspective to it.

MS. ZELLMER: Muin, I would also say that for single-gene disorders, there are a lot of people who don't get genetic counseling who would benefit from genetic counseling. Most of their information comes from their physician, and even, you know, some of the specialized physicians are not very good at giving genetic advice.

I think that perhaps the coverage and reimbursement issue restricts people from getting genetic counseling, and I think a lot of people get their information over the Internet or from whatever they can do to find their resources.

I think that certainly we should do whatever we can do to encourage people, particularly with the single-gene disorders, and perhaps as we move on talking about genomic medicine, hopefully we can worry about the education component and get probably more physicians involved in the counseling process.

I certainly think with single-gene disorders, I think there is a large percentage of the population who does not get genetic counseling. Probably I would guess because genetic counseling is a paid-for service, and it is not getting recommended by physicians.

MS. BERRY: I think we've got some work to do in terms of framing this issue more broadly and incorporating all the comments that we heard this morning. We'll do that. There is some work that was done by SACGT that I think we can lift from and teeing up the issue that will help put context to these recommendations.

So if I can kind of bring us to a close on this issue, understanding the points that everyone had raised, and accepting the fact that we are going to work on language in the substance of the report that provides that level of explanation and context.

Does everyone feel comfortable with these three recommendations as they are currently presented? Any objection? Reed?

DR. TUCKSON: I was just trying to make sure. So an analysis is needed ? - I'm trying to see.

MS. BERRY: It could be more affirmatively worded that we call for.

DR. TUCKSON: So therefore somewhere we call for it, that's the deal?

MS. BERRY: Right.

DR. TUCKSON: Somewhere. It may be at the very end, we are calling for somebody to do something. I guess that's where we're not sure yet.

DR. McCABE: One could just restate that first sentence, "We recommend an analysis to determine which health providers." If you want, because we've lost the IOM piece, you could put in parenthesis, "We recommend an analysis, e.g., IOM, HRSA, et cetera," since we know that HRSA has been doing this, and we may be able to utilize that information. But also perhaps trying to recommend that this analysis be elevated to the IOM level, which would recognize the importance of it to health care in the United States.

DR. TUCKSON: I think that's good. I wish I knew more about, and I wish we all knew more about exactly where is the leverage point. I mean, would it be wonderful if it was as simple as if we then sort of sent the letters to the three organizations who have the most opportunity to come together and nail this thing? Maybe CMS would convene it or something, and we could actually call for that level of specificity.

DR. McCABE: Well, I would remind you, Reed, that in the past, one of the things you have recommended is a czar or a czarina of genetics. Again, that is an issue that I think we have discussed, that the genetics services is really quite fragmented within HHS, let alone the rest of the government.

DR. TUCKSON: What about the committee? The health professions committee at your place, Alan? You guys co-chaired, I think. There were about 30 or 40 organizations that came together. NCHPEG. Is this anything that NCHPEG could deal with? I'm sure it is, but I'm just trying to check.

DR. GUTTMACHER: NCHPEG really is focused on health professional education in genetics. It is trying to be a big tent and invite everyone in who might be interested. I suspect that part of what we're talking about might be to throw some people out of a tent, and therefore, it might be contrary to NCHPEG's very efforts and in some ways compromise its ultimate achievements.

DR. TUCKSON: Well, the IOM, we threw that one out, right? Because first of all, it takes a while.

MR. MARGUS: Because it would be a meta-analysis, Francis said, at a very big picture level only using analyses that other people had already done and drawing them together. So if they exist, we could use IOM. All we needed to do was to do homework to see if it exists, and if they don't exist, recommending IOM would be kind of a -
DR. TUCKSON: Well, let me just maybe do this. I don't know whether, Madam Chairperson, on this if we approve everything else to this point, and then maybe actively solicit from the genetic counseling community, and we also have you as chair or someone else, and we just start identifying potential places to get this study done, and then come back with some kind of a recommendation.

I think what we are hearing is we can't solve this one at the table, but that this is a priority low hanging fruit that we want to knock down between now and the next meeting.

DR. McCABE: The reason why I put IOM back in, I think HRSA is already doing a study. IOM would be a meta-analysis, but it would probably be more back to that 35,000 to 50,000-foot level that we were talking about. What the IOM would do, I think, would identify gaps.

The other thing, the other reason to put it in is a specific recommendation that the IOM doesn't have funding for this. Funding would have to come from someplace. That's the reason to put it in a recommendation to the Secretary, so that there might be a consideration for funding of such a study.

I don't think we're saying that this would be one study necessarily. There might be a variety of studies looking at different levels of the issue.

DR. LEONARD: Right now, those three recommendations are fairly broad, calling for studies. Yet we have heard from a number of people on the committee, Kimberly and others, who say that the current genetic counseling is useful. There is not enough of it, and people don't get paid.

This is, as Emily pointed out, a coverage and reimbursement document. I don't feel like we're addressing the elephant in the room, which is that genetic counselors can't be paid.

MS. BERRY: The problem is, though, just to play devil's advocate, and I agree with you, that in order to get them paid, particularly under Medicare, a case needs to be made. We just can't show up at CMS or at Congress and say, well, we really like these people, they do great work, they should be paid.

They will say, show us why. If the evidence exists out there, the data exists and has been analyzed and collected that demonstrate the value, the effectiveness, the importance of reimbursing for these services, it shall be done. But I don't know that we have that yet. I guess that is what these recommendations are aimed at, at making sure that we've got the information that CMS would require, and that Congress would require. They won't just take our word for it.

DR. LEONARD: But there are at least two states that are going to be licensing genetic counselors. There must be a body of evidence that says that licensure is reasonable. Where is that body of evidence that got those two states to provide licensure? It must exist.

MS. BERRY: But licensure isn't necessarily a guarantee of reimbursement.

DR. LEONARD: True, but it is necessary for reimbursement.

DR. TUCKSON: Again, I think we have some work to do. We need to bring that stuff forward right away.

So I guess, Debra, the question for you would be ? - well, can we go back, Sarah? Remind us on this report where we are in terms of when we want this to hit the streets. Is this supposed to be locked and loaded by the end of this meeting?

MS. CARR: No. The plan was to go out for public comment. I mean, I guess there was some discussion we needed to have about when the committee wants to be able to finalize the report. Is February even possible, or is it going to take until June? Is that what you're asking?

DR. TUCKSON: Yes. So there's no question. So just to be real clear so that we're all on the same page, obviously we don't want this report to take 99 years. Does everything have to be solid, tight, and really terrific before the whole thing goes out? Or can you reference that more work may come on certain parts of it? Specifically, on this one given that we've got some evidence to uncover, a little bit more work to do on this topic, would you be willing to get that work done and see it in the full report, or reference it as stuff coming after the report is released?

How important is this issue to this report, and having this one sort of nailed down with a little greater specificity? The enemy of the good is the perfect. Do you want this particular issue perfect?

DR. LEONARD: I don't think we're talking about perfect. I think we're talking about two philosophical differences. One is to call for a study. I would argue that that information exists. We haven't just gotten it yet.

We could potentially in between ask for an update from Judith Cooksey on the HRSA study and the status of that, look at what has been presented for licensure, you know, and I'm sure genetic counseling ? - Peter was just saying that Andrew Faucett is speaking to us in the public comment section this afternoon, and maybe he's here and could provide information to staff on what information exists.

Between now and the next time we have this discussion, maybe we do need to just say, we need studies. But I would think that if two states are providing licensure, that information is out there. We could get it, and we could then make more specific recommendations the next time.

DR. TUCKSON: Well, explicit in your comment, if I understand it, is that it appreciates that this report will come back for another discussion anyway at the next meeting, and that there is another meeting where we will discuss this. We will all see this again as a full committee. In the interim, certain work can occur.

MS. BERRY: Peter, did you have a comment?

MR. GRAY: No, my comment was just simply to point out that Andrew Faucett was listed as a public speaker so that he may be able to address this issue.

DR. WINN-DEEN: So one other suggestion might be to invite people who were involved in the creation of the licensure programs in, I think it is California and Utah, to come and give us their input. What did they do? What were the studies they used? What were their criteria? What were their goals? Are they already working towards this on a state level? Is this something that we could leverage or specifically recommend the California pilot program be used as the demonstration project?

So rather than just calling for a demonstration project, we might be able to me more specific if we knew more about what was going on at the state level. I mean, to Debra's point, it seems like those states must be pushing towards this for a reason. Not just to have licensed professionals, but probably to deal with the issue that we have before us of how to not just get them licensed and credentialed, but also to get them paid for the services that they render.

MS. BERRY: Not to put you on the spot, but Mr. Faucett, I don't know if you wanted to make any comments now to help inform this discussion, or would you like to wait until the public comment period? What is your preference? We certainly could benefit from your insight on this.

MR. FAUCETT: I'm willing to do either one. Whatever helps the committee the most. Just a quick comment.

DR. TUCKSON: If you could just introduce yourself. By the way, I think this is a good time.

MR. FAUCETT: I'm Andy Faucett. I'm a board-certified genetic counselor, and I'm here today representing the American Board of Genetic Counseling, which currently accredits training programs and credentials about 1,400, 1,500 genetic counselors, the largest group in the country.

In reference to licensure, there are actually three states that currently have licensure, Illinois was recently added to the list. I believe there are 14 or 15 currently working on that process.

It is important to separate the distinction between licensure and billing, and reimbursement. One of the things we all learned is that licensure is to protect the public. It does open the door to billing and reimbursement, but the two should not be directly connected. But I'm here as a resource to answer any questions the committee has.

Yes, Barbara?

MS. HARRISON: I guess just specifically on the literature that is out there showing the efficacy of genetic counseling.

MR. FAUCETT: I'm not sure there is a lot. I know there is some, and I know it is pretty powerful that is there. It might be worth pulling together.

DR. TUCKSON: Do you have any sense of the similarity and/or differences between the criteria that are used by the three states? Is this very homogeneic, or is it state by state?

MR. FAUCETT: All of the states currently are using ABGC credentialing as their process. Some also have to have another door in, because currently to get ABGC certified, you have to be trained in an ABGC accredited program. So some states have to have another door for people to come in, and also a method for people who chose not to get accredited years ago when it was optional, to consider doing that.

The ABGC actually made a statement at a board meeting about a year ago that we would work with any state to provide a program that met their needs. But currently all of the states are using ABGC

certification.

DR. TUCKSON: And the scope of practice also defined, and is that similar state to state so far?

MR. FAUCETT: Yes, it is. I think the only difference is California has a provision about physician supervision, and the other two states do not. I think that is one issue that I think you'll see variation from state to state.

The ABGC accreditation and credentialing process is a competency-based process. So you can go to the website and you can see the competencies that both counselors are trained under, and then the competencies that they are expected to be able to show when they take an exam, or practice as a genetic counselor.

MS. HARRISON: I didn't know if Kelly Ormond from NSGC may have more information about this.

MS. ORMOND: Thanks, Barbara. Having been one of the people involved in the Illinois licensure, I actually was pretty involved in trying to come up with some of that documentation. I will agree that there is not much of it out there. I think that's very important to recognize. So I strongly support this committee's idea of trying to pull together what literature is out there in a comprehensive manner, because that will be enormously helpful for states going through this process.

One of the things that we did cite in our process was the literature that Barbara was referencing, which looked at outcomes comparing non-genetics physicians and genetic counselors, particularly in the prenatal environment. We looked at termination rates and other outcomes in terms of health, morbidity, and mortality. But there is almost nothing about effectiveness or usefulness.

I think that one of the things that NSGC has done recently is we put out an RFP that is almost complete that is looking at developing a prenatal model for genetic counseling, and where you can have impact in trying to develop those sorts of models. We would strongly encourage more studies in that area.

DR. WILLARD: I think we have to be a little bit careful, especially in this conversation, because the issue, and someone correct me if I'm wrong, the issue is not is genetic counseling effective. The issue is is there a difference between supervised genetic counseling in which you can bill under the name of a physician, and unsupervised genetic counseling in which a counselor might be able to bill on his or her own behalf.

So nowhere is the issue of effectiveness coming onto the table here. So either we assume as Muin implicitly did earlier, which is that of course it is important and effective, that is why we all want to do it. The issue is simply do you need to have a physician sign off on it and bill under his or her name, or can a genetic counselor. So am I incorrect in this?

MR. FAUCETT: I would argue that you are, because there are many institutions that don't feel you can bill under a physician. There are many institutions who don't bill for genetic services just for that reason. They provide the counseling services, but they don't bill for them, because the institution doesn't believe they can bill for them under a physician. So it is not as simple as whether or not it is under a physician's supervision.

DR. WILLARD: But that's an interpretation by ? - I mean, when I was running one of these services, we went through exactly that discussion, whether we wanted to charge or not under an interpretation of that. But that's not Congress' particular concern.

MR. FAUCETT: I would say that's the largest interpretation currently.

MS. HARRISON: And I think it is partly up to Congress, because it is my understanding the reason why genetic counselors, and not all genetic counselors, it is not acceptable for us to even bill under physicians, because we're not listed under the CMS allied health, I forgot the wording of it, as recognized professions. So that's one of the issues.

DR. WILLARD: Right, but in the context of this report, it does seem reasonable for one of the gaps that we might identify to say that there is a range of interpretations, and the bar that one has to address and get over as an institution to say, do I want to have a physician who is in the same suite who is literally in what does it mean to be supervising, and is that frankly worth the dollars lost to provide such supervision, versus the dollars you might gain by actually getting reimbursed for it. So it is relevant for this committee to address that particular issue. That is a real life issue that every institution goes through, or every genetic service goes through in trying to meet its bottom line.

The point I was making is that it is not simply a question of is genetic counseling effective. Because I don't think that is either in question, or particularly relevant to the issue of reimbursement.

DR. KHOURY: I'm not sure how to tackle this. We are dealing with reimbursement issues here. We are dealing with the elephants in the middle of the room. I heard that there is not enough counselors out there that can provide services to people that need them with genetic diseases.

On the other hand, those that do provide the services are not reimbursed for them. So we have a Catch-22 here. If we were to commission the IOM report to examine these issues, they would go off in a corner, study this issue for two years, gather data and information, and then write a big report on it.

It would seem to me that this committee would be served by commissioning a paper by somebody, or maybe a smaller subset of the committee, or getting somebody from the outside to write a review of the available literature and here I might kind of defer a little bit you, Hunt, on the ? - I mean, there are many nuances around effectiveness and utility of genetic services and counseling. You can define that any way you want.

We all happen to think it is wonderful and useful. So there is an inherent bias there. If we can through systematic review of the literature, putting all that stuff together with well defined outcomes, I think, and I heard from Andy that maybe there is not enough of that being put together.

I think this committee can go a long way to address the issues of coverage and reimbursement for these services by beginning to pull that literature together and identifying the gaps.

Ed, you said earlier that it is completely ethical to do a study in this area. I never thought that it would be ethical to have 50 people with the same disease, and then put them into two groups, 25 people that you don't provide genetic counseling for, you just give them a diagnosis, or you can have different nuances like supervised versus unsupervised.

I mean, there are many issues that we can talk about. If the fundamental tenant that these services are useful in some fashion in terms of outcomes, even psychological outcomes, it doesn't have to be completely health outcomes, then why aren't they reimbursed?

I think this committee, we are playing the chicken and the egg here. We are in a Catch-22. Somebody has to take that on. If the IOM takes it on, that's fine. But I think we can do a bit of more homework for the IOM by pulling that literature together ourselves, or commissioning somebody to do it.

DR. McCABE: I'd just like to clarify what I said. I wasn't indicating that the placebo would be no

counseling. What I was saying was if we could do controlled clinical trials in an operating room where they are comparing different approaches, we could certainly look at different approaches and identify what is the best approach here.

So I think it was more that it has been unheard of to do clinical trials in surgery, because every surgery was different. But people are beginning to do those now.

DR. TUCKSON: I think obviously we need to move this forward. I think Muin's recommendation is one I think that gets at what we need to do. I would speak in support of it.

As I understand it, what it accomplishes is first it allows us to have the recommendation that's on the board for now. What it allows us to do is to push that recommendation forward with a definitive concrete action that we can sketch out the actual paper, the study, the accumulation of data, and the analysis that we look for. We can do that little bit of detail offline.

It allows us to have something very definitive prepared for us by the time we sit down again. Thereby, that puts an urgency towards moving our agenda forward. It gets us off the dime today, because we can't solve this problem today, because we just don't know enough to be able to resolve it.

DR. LEONARD: Would you two be willing to work together to provide and work with staff to provide as much of this literature in some sort of summation form with the papers ? -

MS. ORMOND: Absolutely.

DR. LEONARD: ? - to this committee by some point? It wouldn't be our next meeting. It would probably be slightly before our next meeting.

MR. FAUCETT: Yes.

DR. LEONARD: As well as then I don't know whether Judith Cooksey can provide some information on the HRSA study. But I think those two sources we know are out there and could be used to inform our discussion next time to be able to make more definitive requests.

DR. TUCKSON: So as I hear Debra's point, it is that the project leader for this, and I think this still fits, Cindi, within your team. Cindi, I think that your team is taking responsibility for pulling that paper together. I think what we've gotten is a commitment on the part of two major stakeholders to be at the forefront of helping us to shape that paper, providing information, guidance, and so forth.

Not exclusively those two, but the others that will probably be added to you. You are truly two linchpins in all of this. I think we all appreciate your willingness to do that. Then we'll let the committee under Cindi's leadership determine others that need to be involved.

Muin Khoury, if you're not on the committee, you are tasked to provide help.

MS. MASNY: And I think, too, that maybe what we could also do is ask the International Society of Nurses in Genetics. I know that they were keeping a running list of all the studies and literature that were done by nurses in the field of genetics. So that may also add to this.

MS. BERRY: So for now, in the interest of moving this forward, I propose that we leave these three recommendations as is, with the understanding that we are going to be in the process of selecting information from the folks who are here today, from other organizations, analyzing that, talking to HRSA,

finding out the status of their report, and then we may after that be in a position to propose some changes to these recommendations in addition to the substance of the report where these recommendations are found.

DR. TUCKSON: That sounds good to me. Terrific. Thanks to both of you for stepping up to the plate like that on no notice.

MS. BERRY: Moving to the clinical laboratory fee schedule issue, we have heard time and time again from the public and from other stakeholders that oftentimes the costs of providing these tests exceed what Medicare will pay. Remember we are still in the context of the Medicare program.

Lab fees, as we have heard previously, are frozen. So there is the real danger that for the foreseeable future, we will have this gap between what it costs to provide these tests, and what a lab can be reimbursed, thereby providing a distinction for the provision of these services.

This recommendation is not without controversy. The idea was to set up some sort of temporary mechanism for addressing some extreme discrepancies between the cost of delivering the service, the test, and what Medicare will pay. This is the inherent reasonableness capability, I suppose for lack of a better term, that CMS could exercise. But there are some concerns with using this approach. Is anything really temporary?

Some people would view this as a slippery slope. Is this a dangerous course to take? It was the only recommendation that surfaced to address this problem given the fact that we do have a freeze. Payment rates set by law are difficult to change.

So we'd be very interested in hearing from individuals who are most directly affected by this as to what the thinking is on this sort of temporary approach to addressing some of the most extreme cases.

DR. LEONARD: I found very interesting the article that was provided to us I believe by AdvaMed. It was by Gregory Raab and Joan Logue. It is astounding to me to look at some of the discrepancies that exist across the board in the laboratory fee schedule as implemented on a state level.

They had some recommendations at the end of the article that they would be more generic than just genetics. If we want to just do the inherent reasonableness for genetic tests, we are talking about 14 CPT codes, billing codes, and the reimbursements for those. This would be a much more limited and directed effort that may be possible to accomplish.

I just don't know whether CMS is willing to look at just those 14 codes in the absence of looking at the entire laboratory fee schedule, which is a disaster. Well, it is not very good, and hasn't been looked at for a very long time. CMS the last time they were here said that it is the oldest fee schedule in existence.

DR. WINN-DEEN: I wonder if we couldn't be a little bit more firm in our recommendation rather than just sort of asking CMS to look at this again under inherent reasonableness, but to say specifically that we believe all states should be reimbursing at the national level today so that we don't have uneven playing fields among the 50 states where we know that even the national payment schedule is not really covering costs.

I don't know if we have the flexibility as an HHS committee to try and tell states how to implement Medicare programs, but I mean I think that is the first level of inherent unreasonableness that we see when we ask our lab colleagues to come and talk to us about ? - it just seems very capricious and arbitrary.

MS. BERRY: But you're not talking about ? - this isn't the Medicare section. There isn't any deviation, is there, at the state level for Medicare reimbursement?

PARTICIPANT: Oh, yes.

MS. BERRY: But how is it that Medicare wouldn't be directly paying?

MS. GOODWIN: There's a national limit for each CPT code, and then local carriers have the discretion to pay up to that national limit. But certainly it can be lower than the national limit. So that is where the local carrier variation comes in.

MS. BERRY: Okay.

DR. McCABE: Actually, from what I know, it is not completely by state, but it is more by region.

MS. BERRY: Region.

DR. McCABE: That's the way the local carriers are. But there is quite a bit of variation from one carrier to another. One carrier may deny services that another finds quite reasonable.

So I think the system, this inherent reasonableness, while it sounds like a bizarre bureaucratic term, is in fact the mechanism for trying to address the lack of uniformity from region to region. So while it sounds bureaucratic, it is bureaucratic, but it is the way the payments work, and the way the approvals are set. So I think it is a fairly concrete approach to address a problem and need.

DR. LEONARD: But when you do this process, I don't understand it well enough to know what the impact is at the state and local level. This would be a national decision. So I don't know what impact that would actually have in practice at the state and local level.

DR. WINN-DEEN: I guess that was my concern was that if even today with a national coverage amount that is not taken up by all regions, you know, and we all know that even if you got reimbursed fully for every test at the national coverage amount, that you are not making any money delivering these services.

So it is a question of how much are the labs losing money every time they deliver a test result? I mean, I think the least we could do is ask the states, regions, or whatever, to step up and be reasonable.

MS. BERRY: Wouldn't it be that CMS would issue a guidance to the carriers that would assist in the implementation of a more fair fee schedule? In other words, the goal would be to eliminate the great variation that would exist between regions, and it would be done through a guidance issues by CMS?

DR. McCABE: CMS isn't here, so we're left a little bit in the dark. I don't think CMS is here.

MS. BERRY: Oh, yes.

DR. McCABE: So could you help us understand what the impact of this would be? My understanding is that it would provide a central guidance. It would still be up to the local carriers as to whether they pursued that. But by giving it some increased visibility at the federal level, there might be an impact by the local carriers. Could you clarify that, please?

DR. ROLLINS: Yes, that is correct. Essentially the local carriers have the discretion to make a decision based on what they feel is reasonable. It is true that there may be some discrepancies comparing one

region to another.

To make the request that CMS review the extremes in terms of the variation, I think, is a reasonable request for something for CMS to evaluate.

DR. LEONARD: And it is okay to just look at the 14 codes that relate to genetic testing and ignore the rest of the laboratory fee schedule? That's okay?

DR. ROLLINS: I think restricting it to the 14 codes is a reasonable request.

DR. LEONARD: Okay.

MS. BERRY: Any other comments? Ed?

DR. McCABE: Madam Chairperson, can we invite Dr. Rollins to sit at the table so that we can have his counsel in future discussions?

MS. BERRY: Absolutely.

DR. ROLLINS: I'd be glad to. Thank you.

DR. McCABE: I think there is a spot for CMS at the table.

MS. BERRY: If there are no objections, should we close this one out? Leave the recommendation as is? Or are there any changes in the wording that anyone would like to propose before we move onto the next section?

DR. LEONARD: I would like to make it a little more forceful and not CMS to assess, to determine whether fees should be changed, but to basically ask CMS to use the inherent reasonableness to look at the CPT codes and reimbursement that are used in genetic testing, and assure that the current reimbursement level at least covers cost.
That would require input on what it costs to do the testing, but right now it doesn't cover costs.

DR. WINN-DEEN: Can we capture the whole local versus national issue somehow on that, too, to encourage all local providers to come up to the national level?

MS. BERRY: Something to the effect that CMS, or that we're directing CMS and requesting CMS to use inherent reasonableness to examine the variation in payment rates or reimbursement rates for genetic tests and laboratory fees with a view towards ensuring that the reimbursement level in all regions of the country at least cover costs, or something like that.

DR. TUCKSON: I don't know. Just as a minority, I think that we want to be careful. Sometimes I think we want to obviously signal that we have a bias as it were about something. In this case, I think what we ought to be doing is signaling that we have a concern about this, and it needs to be studied in a clear and dispassionate way. You're talking some very complicated issues around money.

For us to conclude in the recommendation that these things are not, you know, that what we want is ? - I mean, this sort of signals the way it says is that we expect them to pay more money. I think we just need to be a little bit careful about being too passionate about that and let them do their work and see where it comes. I may be in the minority there, so I'm drawing that out.

DR. ROLLINS: I think that the request in terms of what is currently on the board is very reasonable. I think that to go beyond that is something that I myself feel that I could not make that commitment. But I do think that that is something that will be studied. If it was felt that there was a marked discrepancy and it needed to be addressed, then that is something that CMS would address in the future.

DR. LEONARD: I guess what I wanted was if there is a discrepancy found, that they fix it. They could do all the studies in the world and say yes, it is broken. And there we would still sit.

DR. ROLLINS: And I would respond and say I hope that corrective measures would be put in place.

DR. WILLARD: I just want to make sure that we're making adequately the case prior to this recommendation, that in fact there has been a harm and a foul. So other than what I accept fully, laboratories have a tough time making ends meet, and they are under budgetary pressure.

From the Secretary's standpoint, I'm not sure that is very high on his personal agenda, unless we can argue that because laboratories are under-reimbursed, or if it is found that they are under-reimbursed, that that actually has an impact on health in this country. The tests are therefore not being taken advantage of, or not being provided to members of the public who should be taking advantage of those tests.

Unless we make that case, I'm not sure the simple issue is we want geneticists and pathologists to be able to make the money that they would like to make. I'm not sure that that will resonate terribly well, no matter how well it is stated.

DR. LEONARD: But maybe we could take a 5,000-foot view on this one, too. Which is if we are moving toward genomic medicine and this is going to have such high penetrance in the entire practice of medicine, then it is a big problem that laboratories don't get even paid what it costs to do the test.

DR. WINN-DEEN: I think we've heard some testimony before this committee, and we have another commentary in here from LabCorp, which is one of the largest reference labs in the country that it is a problem, and that the choice they have is to bill the patient for the difference. I don't think it is too big a leap of faith to take that jump that some patients won't be able to pay that.

DR. WILLARD: I personally don't disagree. I'm just suggesting the committee needs to connect those dots in the report so it doesn't seem like just a request for more money for those providing the test. That's all.

MS. BERRY: We can perhaps take a look again at the language and the substance of the report just to make sure that it forcefully enough states the case that you are articulating. We're not just calling for change in reimbursement just for giggles. I mean, there is a compelling need there related to access, and it falls within the reimbursement charge that we have in doing this report. We'll take a look at that and beef it up if necessary. That will be presented to everyone once again.

Just to tie this up, we floated some language, but it sounded like Dr. Rollins was a little uncomfortable with the revised version. Should we go back to the recommendation as currently stated? Or are there some tweaks that would state what we need to accomplish, and CMS would nevertheless be comfortable with it?

We don't want to recommend something that is not going to be implemented. That will produce no benefit at all.

DR. McCABE: Well, I think we heard that CMS would be most comfortable with the language as it is on

the board. I think we could put the rhetoric into the text. Not of the recommendation, but of the logic that concern has been expressed to this committee regarding the ability for the laboratory to mute its expenses, or something to that respect. So I would put the rhetoric in the report and leave the recommendation for discussion.

MS. BERRY: Any objections?

(No response.)

MS. BERRY: All right. Let's move on to Medicaid and SCHIP.

DR. LEONARD: Could we go back one second? You may just want to say in there so that you are defining the ? - to look at the specific CPT code. The ones that do exist, so you're not talking about ? - well, maybe that's implied by genetic test laboratory fees. But it is a limited scope that we're asking them to look at.

DR. WINN-DEEN: So you just want to add the 10 or whatever?

DR. LEONARD: Existing CPT codes, or whatever. Never mind.

MS. BERRY: We'll fix that.

Medicaid and SCHIP barriers. Of course there is a great deal of variety from state to state, because each state has its own programs with regard to Medicaid and children's health insurance.

There are some reports that we have heard about with regard to instability and coverage for genetic services. States are having difficulty balancing their budgets. So we had two recommendations to propose for the committee's consideration.

One would be really an information dissemination function for CMS that states could benefit by HHS providing the states with information, the best information, and establishing the solid foundation and evidence base for covering and providing genetic services.

The idea being that if presented with this information that they may or may not already have, that the states would be more likely to cover these services in the programs that they implement. The second recommendation is a little bit more of a carrot which would be to provide states with actual incentives, presumably financial incentives, to cover genetic services that are warranted by the evidence base.

That is a little bit more difficult because it involves money that may not be there. But those were the two potential recommendations for encouraging states to provide these services, and covering these services. Recognizing that we really aren't in a position to mandate that these services be covered.

Does anyone have any comments on these potential recommendations? Like them? Hate them? Revisions? Debra?

DR. LEONARD: Do we have an idea of where this evidence base is coming from? I mean, maybe we should put e.g., EGAPP, or other HHS initiatives that may inform what is going to be provided to states as examples. Maybe HHS representatives could inform us about which programs to put there as examples that could inform this.

MS. HARRISON: And then to add to that, whatever we're able to uncover about genetic counseling

specifically. That tends to be a great challenge with Medicare, or Medicaid, rather.

DR. TUCKSON: I guess I'm a little confused on this one in terms of this incentives business. I mean, we've got a $50 katrillion deficit, and HHS, I mean, boy, I'm just trying to figure out what would be the financial incentives that they would ? - how would they think through that? I mean, what do you do when you get this recommendation?

If you just have a sound evidence base, is it a priority? I mean, do you provide the incentive for this and not the first trimester prenatal care clinic in Delta Mississippi? I'm just not sure, how are you asking them to think this through?

I mean, there is no new money, so they are going to take it from someplace else. So how do they think about this?

MS. BERRY: Again, I'm going to throw this out there, because this has worked in the past. My own view is it is not a realistic recommendation in this current budget environment. We have put them all out there for everyone's consideration.

We could, using precedent, recommend that there be some sort of a grant program. I mean, I know that the Secretary has issued grants for information technology, for example, unrelated to this, of course. But there can be state and local communities that would benefit from a grant that would provide an incentive to offer these services. Again, we would have to answer your question, which is right on, of course, Reed, which is does this rise to that priority level, given all the other services and needs that are out there.

DR. WINN-DEEN: I guess I have a little problem with recommending grants when we don't even have a standardized newborn screening program which we know works, and we know there is a lot of evidence that that pays itself back. We as a country have not been successful in taking some kind of a national minimum standard approach and disseminating that out.

Right now we are being embarrassed by the March of Dimes into trying to do that. But they are really leading the charge, the federal government. So I would feel comfortable with us saying that, you know, when stuff gets to a certain level of evidence, whatever that is, that then that information should be disseminated to the states, and the recommendation from the federal level should be that all state programs adopt that.

Whether they are able to adopt it immediately or they have to think about what the tradeoffs are within their budget, you know, I don't think we can really propose anything more than guidance to the states.

Maybe Suzanne, do you have more information? Are there any grants for newborn screening or any other kind of underwriting for basic programs like that?

DR. FEETHAM: I have a summary of that from MCHB for '05, and what they have done in '04. Also, Reed Tuckson is our representative from this group on the Committee on Heritable Disorders and Genetic Diseases in Newborns and Children. That report is in process now.

It is my understanding that it specifically will advise the Secretary regarding the universal newborn screening technology tests and programs. So we may have more to say about that.

DR. TUCKSON: I think with the issues that are on the table are, if I understand it, first is we've got enormous state variability in terms of various mandates for programs, and it drives anyone nuts. The evidence is there, or it isn't there. You've got all this up and down all over the states.

We have clearly got here the idea that there is as a priority area of genetics, particularly since we put SCHIP there, which means the children, is that you've got the Newborn Screening Act, which is all over the place. As you said, what you'll hear, and we have an official liaison to that committee, is that you'll see that every state has ? - it's all a complete mishmash of stuff in terms of what kids are getting access to or not. So they are trying to rationale and streamline that out. That might be a good place to sort of start.

But I think the final thing is that for at least as a perspective for our committee, maybe one of the things we ought to be calling for providing is some sense of a common evidence basis that can inform the decisions that people make, as opposed to saying you ought to provide incentives for covering things that have an evidence basis.

That there are decisions that people have to make based on their priorities. I think the only way this will make sense to the reader is if we give some tangible examples of the kinds of things we're talking about here.

DR. FEETHAM: Also, to add to that, MCHB provided funding last year for regional newborn screening and genetic collaboratives. There were seven regions funded with the National Coordinating Center located through the American College of Medical Genetics.

So again, it is recognition of the issues that you're saying that this funding is in order to try to address the issues you're talking about of the disparate distribution of the services. Again, that is just responding to the fact that MCHB is funding these types of efforts.

DR. McCABE: And NICHD has recently begun an initiative in newborn screening and has recruited former chair of pediatrics at the University of Miami Rod Howell to take that on. So I think this is a broadening. It is a recognition within HHS of the importance of newborn screening.

With two agencies taking an active ? - well, actually three, because CDC has for a long time had quality assurance activities there, and there may be others who I'm not mentioning. But I think there is a broadening recognition that newborn screening as we've heard before, will be the leading genetic testing for the next decade. Most likely with 4 million babies born every year, and every baby having somewhere between 4 and 30+ tests, this is a huge genetic testing undertaken. It certainly needs to be standardized.

DR. WINN-DEEN: Do we want to make a specific comment that we support current efforts underway to achieve a standardized level or nationalized level of newborn screening as a good starting point for that?

DR. McCABE: Not to get into turf issues, but I think it is a bit of a turf issue. There is another Secretary's Advisory Committee. I think that we probably ? - I would think it would be more appropriate for that group to report to this committee and after such report, then go forward with the recommendation. I think it would be acting on hearsay at this point not to have a formal relationship and a formal report.

MS. CARR: Actually, during the last session of the day, we were going to consider other topics that could come up in February. Chris Hook, who is not here today, but very interested in newborn screening, had actually suggested that we have a presentation from that committee about their recommendations. So we're going to talk about that later today. Or we can decide now if you'd rather, to for sure have that in February.

DR. KHOURY: If we're talking about disseminating evidence base for genetic testing services in general, maybe I missed part of the conversation. I think there are ongoing efforts other than the newborn screening area that are going on with states.

The CDC has funded four states in chronic disease programs to begin to take a look at these things, sort of what you are alluding to here, trying to figure out how genetic testing and services can be used outside the scope of the traditional MCH arena in genetics. We have funded schools of public health to begin to build that evidence base and provide technical assistance to state chronic disease programs. So that is sort of another thing in the hopper.

MS. BERRY: Would everyone be comfortable if we kept the first recommendation subject to any revisions or tweaking that anyone might want to propose, but eliminate Number 2? I have sort of heard mixed things.

One is that, you know, the budget reality is such that it would be difficult for us to propose or for the Secretary to offer actual dollars to states. On the other hand, there are grant programs that currently exist, and we don't want to impede that progress.

I don't think an omission of Number 2 would necessarily have any adverse impact on the existing grant programs. But what are people thinking in that regard?

DR. WINN-DEEN: Well, I think maybe what we need to do is just change the words from "incentive payment," which is in my mind like a little carrot that you're holding out to actual specific grants, which is I think what is actually happening to provide demonstration projects and to assist in getting some of these things implemented. I think that might be more reflective of the actual practice within HHS, which is already happening. There is obviously some funding set aside to do that, so I would be okay with that.

DR. LEONARD: And it could be worded that HHS continue to provide states with support or grants, indicating that they are doing that by various mechanisms and continue to do that to implement the sound evidence base of testing.

We've narrowed this down to Medicaid and CHIP. But if you look at adults, we want genetics to be used on an evidence-based mechanism for all of genetics. Do we want to broaden this potentially? Would there be any utility?

Muin, I know you're looking down, so I can tell you're working on your blackberry, so I'll get your attention first.

DR. KHOURY: I know how to multitask.

DR. LEONARD: Yes, but this wasn't one of the tasks.

DR. LEONARD: So is it useful making recommendations at the state level for Medicare? Maybe this is more CMS, but you are the one that is generating those evidence bases. So could we broaden this to be Medicare/Medicaid/CHIP coverage decisions? Because I don't know how much Medicare is at the national level versus also being influenced at the state and local levels.

MS. BERRY: Well, later on in the report as well, just to remind everyone, there is the section that deals with all payers. So there are some recommendations that we're going to be working on which address and get to the evidence base, that get to how do we make these decisions? Who covers what under what circumstances? So I don't know if that is a good place to get at your point.

DR. LEONARD: Maybe something once we work through all these recommendations -- I'm getting the feeling that they're not lumped. This is the process you have to go through is you take the body of what you have written and you kind of duplicate that in creating recommendations.

But like the UPIN for genetic counselors could go with the genetic counseling if there is stuff on Medicare and private insurers, maybe this dissemination could be lumped all into one recommendation so that we don't end up with 50 different recommendations if we can lump them and make fewer, it might have greater impact. Even if it is down the road after we work through absolutely all of these individually.

MS. BERRY: It is quite possible we may have to ? - well, we are already reorganizing the paper from yesterday's discussion. So we will definitely need to do that after we get through these. So any final thoughts? So what I heard then most recently was we keep Number 1. Number 2 we revised slightly to reference the fact that HHS is already providing some grants or some assistance to states, and we would urge them to continue to do so. That gets us away from HHS must set up some new program and provide actual dollars to people, but more it is an encouragement of existing policy, and to the extent possible and feasible, they could expand that within their discretion.

(Recess.)

MS. BERRY: All right. We are now in the section where we are addressing barriers that apply to both public and private insurers. The first section in this part of the report deals with the fact that Medicare is often a model in many other circumstances for private insurers.

So to the extent that Medicare has coverage and reimbursement problems with regard to genetics tests and genetics services, it could have a ripple effect and an adverse effect on coverage and reimbursement in the private sector.

However, as a task force, and as a committee in the past, we've struggled a little bit with this because while that may be true in many other fields, it does seem, because we had heard some testimony and received comments from folks in the private sector, that in the area of genetics, many times the private insurers are a little bit more advanced than Medicare, because they don't have some of the same legislative constraints that shackle CMS in terms of what can and can't be covered. So, for example, the screening exclusion that doesn't really exist in many private health plans.

We recognize that Medicare is often a model, and so that is one additional reason for changing or facilitating changes in policies that would expand access coverage and reimbursement for genetic technologies. We struggled a bit with what the recommendations should be.

This isn't really in the form of a recommendation. It is more of a statement which basically says that private insurers should not wait for Medicare to make these determinations, and that they should essentially without directly saying it, make their own decisions based on the evidence base.

This may not be worthy of a recommendation, because it is sort of a declaratory statement. We talked also about possibly advocating for some outside organization, whether it is AHIP or some other entity, to develop voluntary guidelines, or some standards that would not be mandatory, but that would be a model for other private insurers to adopt with regard to genetic tests and services.

We didn't put that up there. This is one that we struggled with, and we could certainly benefit from the committee's views on.

DR. McCABE: I think it's quite good. I think it is important for it to be there. It is a declarative statement, but that is what a recommendation is.

I would just make a couple of minor wordsmithing things. The last line in the book at least, let me just

read the second sentence. "Such services should be considered specifically with respect to the benefits." Let's be positive. To the benefits, they offer the populations they serve. I'd get rid of "different" also. I mean, I just think we waffle what they can offer. If there are benefits, then they should provide those benefits to their clients.

DR. WILLARD: I would disagree with Ed, only from the standpoint that we're providing recommendations to the Secretary. So having it in the text as a discussion to provide background is fine, but to make a recommendation to the Secretary that others who are well beyond his reach should be allowed to do what they want to do seems like an odd thing to be doing.

MS. MASNY: I was just going to comment that since we have been talking so much about evidence-based practice, that many of the health insurers now have their own technology evaluation committees, that maybe in the text, as Hunt was just saying, we could say that with their own appropriate evidence-based review, that genetic tests when appropriate, that they don't have to wait for Medicare. They could move ahead with the testing.

MS. BERRY: Now, I will point out that later on in the report, and we'll get to that, there is a section -- and in fact we're going to restructure it even more than what currently exists in front of you -- there is a section on information utility, the preventive nature of genetic services, factoring costs into coverage decisions. There is another thing that we are talking about moving.

It all leads to the evidence-based discussion. The recommendation there, without jumping too far ahead, deals with HHS establishing some sort of working group to come up with a set of principles that would help guide insurers, public or private, in determining what should be covered, when they should be covered, and when certain services and tests should be covered, that kind of a thing.

So I don't know if that could serve as a recommendation for this scenario. Maybe we are lumping instead of three or four, it is all five of the barriers that have been identified, this being one of them, and have that recommendation serve as the recommendation for all four or five.

DR. McCABE: I understand the reason for removing it as a recommendation to the Secretary. I have no objection to that. But in the text, let's make it clear that we recommend that private insurers not wait for Medicare. So let's make it clear, because I don't want to give the private insurers an out that until Medicare is ready, we're not ready.

If we do that, then we need to also look at the other recommendations within this section, if we're going to go by that principle. But we can state them as recommendations, highlight them in the text somehow, but not as a recommendation to the Secretary.

MS. GOODWIN: I think to get to Hunt's point, and also Ed's, certainly the direct audience that this committee has is to the Secretary. But certainly I would like to remind you that you also have a national audience. While you might not have as much weight in addressing it, this report is going to be available to the public. I would hope, especially in addressing the various barriers in this section, you would keep that broad audience in mind and not feel limited in any way to addressing your recommendations to the Secretary. I hope that provides some clarification to you as you work through some of the issues. Certainly this topic in particular has broader relevance than just Medicare. I hope that you don't just feel limited to crafting any recommendations directly to areas that the Secretary has control over.

DR. TUCKSON: Yes, two things. I think first that last point, that last dialogue is important. I continue to come back to the idea that the committee will be best served by focusing as much as possible on its priorities. If we're just scattershot all over the place, we are not going to be as effective as we would be if

we focused in on things that are the most important.

Having said that, I think that the recognition that there is a broader audience than the Secretary that we do speak to is important. I think we shouldn't speak only to those things which the Secretary ? - maybe we might want to bring it to the attention of others, or in the course of our deliberations, we have uncovered this important issue.

If it is important enough, we may want to speak to it. The only issue I have with this recommendation here is that the private sector, as the text says, is doing these things. I think we want to be careful that if we're going to make a recommendation that it doesn't look insulting.

You know, the way it appears now is as if the private sector was simply not doing anything and waiting for Medicare to act. That is not what the text says. So I think you want to sort of maybe encourage them and so forth.

The other thing is if we're going to add the insurers on this one, it is also the payers. The way in which we set this up in the earlier preambles, it is the combination of how you get to these things is ultimately determined by the purchaser, and the plan. So it is all of those folks working together.

I think the final point is just really grounding this stuff. Again, evidence basis, and priorities.

MS. BERRY: Does anyone have any suggestions as to whether this should stay as a stand-alone piece with this recommendation as revised by some of the comments we just heard, or whether it should in fact, and perhaps we can't make that determination until we get to it, but lump it in with the other section which has a recommendation dealing with evidence base? Does this merit really standing alone in isolation because of the critical importance of a statement that we want to make here? Or can this be merged in with the other items? Does anyone have any strong opinion?

DR. LEONARD: I think given that private insurers are to some extent at least doing this, I don't know that we need to stand alone. I think by incorporating this into the evidence-based section, we can still make the same impact and have fewer recommendations overall.

MS. BERRY: I think that's a good approach. Does anyone object to that? So we would remove this recommendation, but merge it in with the other section dealing with evidence-based practice. We would still retain the text, it just would be in a different section.
Hearing no objection, that's what we'll do on that section.

We also had discussed very briefly the UPIN issue, and discussed moving it into the section that we addressed earlier, genetic services and counseling. So it wouldn't be a stand-alone here, it would move into that section. So we can still go into the recommendation, but just know that it will be moved into the earlier section that we talked about.

This is an issue of course that identifies the fact that genetic counselors are not eligible for a UPIN, and that many health plans use the UPIN system. So if you're not eligible for a UPIN and the health plans use that system, that may adversely affect the ability of genetic counselors to directly bill private insurers.

The recommendation would be until the national provider identifier system is implemented, that perhaps private health plans could create their own provider numbers for genetic counselors to use for billing purposes. This also falls into a similar type of situation as the earlier recommendation.

Well, it is a little bit more of a recommendation than a declaratory statement. But I think health plans do

know that they are at liberty to set up their own numbers if they wish. The question is whether the committee feels that it is important to make that statement, and urge them to do so.

DR. McCABE: I would make the statement, but I'd include it in that string, I think it would be Number 4 then, if I recall, 3 or 4 in that string that we had that we started the morning off with.

DR. LEONARD: I would say that this potentially could be informed by whatever information is brought back to the committee at the next meeting, and we can move this one up there. But there are certain steps that will have to be taken in order for genetic counselors and those providing genetic counseling services to bill and be reimbursed for those services that are currently going on.

If this is one of the steps that needs to be done, then maybe information could be provided about how that would happen. So including this in that discussion would be useful.

MS. BERRY: Suzanne, do you have what you need? All right. The next three barriers that have been identified, there is not one recommendation that will come after each one. You'll see in the report they are lumped together. The recommendation would apply to all three.

It is informational utility and medical effectiveness as one issue. The next one is the preventive nature of genetic services, the third is factoring cost into coverage decisions. Those three things after discussion in the report, they lead to one recommendation which we'll get to in a second. But I wanted to call your attention to that.

This one, the informational utility medical effectiveness piece focuses on the fact that health plans use medical effectiveness to make sure that the services that they cover meet evidence standards. It also in the text discusses the fact that there are some genetic tests and services that people may find useful and informative, but may not warrant coverage because of the medical effectiveness criterion. This raises the issue about whether informational utility on its own really warrants coverage.

The second barrier deals with the preventive nature of genetic services, highlighting the fact that of course there are long-term benefits to providing these services, and they can be cost-effective over the long haul. But in the short term, because people change health plans, that's one reason, coverage for preventive services might be difficult to justify, and insurers may or may not feel that coverage would be warranted.

The third barrier issue that is addressed here in this section deals with the fact that there is some uncertainty about whether and how best to incorporate cost-effectiveness data in coverage decisionmaking. There seems to be a lack of data on cost-effectiveness of genetic tests and services. That has potentially an adverse impact on health plan coverage decisionmaking.

So we came up with a recommendation that potentially could address all three of these issues. That would involve the Secretary tasking an appropriate group or a body establishing a task force so to speak that would develop a set of principles for coverage decisionmaking for genetic tests that would assist employers, and it would assist health plans.

It wouldn't be a mandate, it wouldn't be a requirement, it would be more in the form of guidance. These principles would identify criteria that would help health plans and other payers determine when should genetic tests be covered. When should they always be covered? Which tests should never be covered, at least under the current evidence base. Which genetic tests fall into that gray zone where it might need to be determined on a case-by-case basis?

Cost-effectiveness could be addressed here, as well as the preventive nature of genetic tests and services.

Again, emphasizing that this would be more on the lines of guidance. I don't know to what extent some of this work is already being done. We might want to reference that. Does anyone have any suggestions, comments, or thoughts?

DR. KHOURY: Maybe you can help us flesh this out a bit more. I thought the set of principles related to genetic tests have been kind of set forth by SACGT earlier, sort of the ACCE paradigm. But it didn't go far enough with respect to reimbursement.

I mean, it basically talked about the issues that need to be considered when a genetic test is being looked at from the analytic validity, all the way to the ELSI issues. What we have taken with the ACCE project and the EGAPP project is tried to move the ball a bit further down the field, if you will.

I think where you end up in a stumbling block is what is that threshold at the end of the day when you have collected all the information and identified all the gaps? Then the principles around the criteria for what to fund and what not to fund is always a sticky point.

So I'm struggling with a notion here, and maybe others can help by jumping in. Identifying the principles which I think SACGT and you and others have kind of ? - I mean, it is easy enough to say these are general principles, but how to move them forward with the question of threshold. That is a more sticky point. I'll just stop here, and maybe collect my thoughts more.

DR. LEONARD: I don't understand how this is different than the ACCE and EGAPP. You have to provide information about specific tests, their utility, what they do, when they should be covered, what populations, and I think that is what ACCE and EGAPP are doing.

To me, this sounds like not only you're going to provide that information to Medicaid and SCHIP and Medicare and private insurers, I mean, you basically want wide distribution of that information coming out of ACCE and EGAPP. I think that is what is being asked for here.

I don't know that we can do the cost analysis. I think each provider has to figure out what they can pay for and what they can't. But once it is medically useful, more than likely it will be paid for by some groups, an increasing number of groups over time.

DR. ROLLINS: I think you may want to consider either removing cost-effectiveness, or putting it at the very end, only because health plans usually don't take into consideration the cost of a technology, at least at the initial assessment.

I think that that would give the impression that cost was being taken into consideration for a plan to consider a particular technology. So either eliminate it, or if you want to keep it, I would stress it as the very last component of that sentence.

MS. HARRISON: I just want to make sure I understand. Are groups like EGAPP, which I guess is under ACCE, or follows an ACCE model, are we saying that we don't really need to establish a group then? That there already
is a group established?

MS. BERRY: Well, that's the question. Do we feel that the work that is already being done, is that sufficient? Does that provide sufficient guidance from our standpoint to health plans and pairs? Or does there need to be a new group that kind of synthesizes and brings together all of the work that is currently being done, and perhaps fills in gaps, and then serves as a guide?

DR. KHOURY: It seems to me that this committee can make a recommendation to HHS along those lines, because EGAPP is an experiment. Three years from now, it will disappear. Whether this could precede or secede, or be part of EGAPP, or EGAPP could be independent, it doesn't matter.

I think HHS should take the lead, and all the agencies presented here can come together, beginning to take what has been done so far, and then melding it into the set of principles. Then the agencies can figure out how best to work together, or HHS can tell us.

Because we have been struggling with this for a long, long time. I mean, starting with Tony Holtzman's NIH/DOE task force. I feel like every year we make a little bit more progress in this area. Where you get at the end of the day, you get at the stumbling block of people looking at the same data, but making different conclusions with respect to reimbursement and coverage.

Depending on where you set the bar, you want more or less medical effectiveness versus other things. For example, there is a clear distinction between what the U.S. Preventive Services Task Force, and my friend here is not here to defend himself, with respect to the very strict criteria for clinical utility, versus some of the other models of technology assessment, including ACCE that have been proposed.

That is why what we wanted to do at the beginning of the EGAPP project is to put all the methodologies together and try to come up with hopefully a consensus methodology for how these evidence-based reviews can be done. Because again, as I say, it is a step along the way. But if you push HHS to keep its appropriate leadership role in this area with all the agencies contributing to this effort, I think that would be a wonderful goal.

DR. TUCKSON: Yes, I guess I'm struggling with this one as well. I think maybe Muin got us there. I can't quite tell what we are doing. Let me ask specifically.

Are we taking a position that is an advocacy position that says that at the end of the day, what we want to see achieved is for tests that do not have a therapeutic import, we want to make sure that those tests are covered? We want to see them pushed. Our real issue here is to push in a certain direction for certain kinds of things to get covered.

As a result of that, we are sort of dictating that direction. Or are we saying, this is a complicated world where there are new issues that emerge because you've got diagnostic tests out that are predictive in value that may not be related to therapeutic interventions per se.

As such, it raises the need for information to be readily available for decisionmakers to be able to make appropriate decisions. The categories of information that must be made available are evidence basis of work, you know, the clinical utilities and so forth and so on, cost-effectiveness of what it means to implement this, how this new test relates to existing, if there are any ways of evaluating that disease condition, and so forth.

So what we are ultimately trying to assure is that people who have to make tough decisions have a knowledge base from which to make it. I can't tell whether it is that we view our responsibility as ensuring that a knowledge base exists in a set of areas that are decisionable, or are we saying no, what we want to do is have a knowledge base that allows certain things to actually happen because we want these tests to be implemented today. I can't tell which one we're asking for.

MS. BERRY: Also, I think, and just to mention again, later on in the report, we talk about the evidence-based issue, evidence-based coverage decision. In that section, there are recommendations which include HHS to task a group to assess the evidence for specific tests and determine whether the evidence is

sufficient.

You can make an argument that that whole discussion as you outlined the latter point, not your first point out ? - I don't think we're going in the direction of we should cover everything, no matter what it is, whether it leads to some potential therapeutic benefit or not. I don't think we're there, but more the latter point that you raised, Reed, which is there may be some need to provide guidance in assessing all of these factors may be that we merge this section in with the evidence-based section and take a more global approach.

DR. TUCKSON: And I think maybe the way also, that sort of makes sense to me. What we sort of say is a reasonable, prudent analysis of this new world that we're in means that these new tasks must be considered by any reasonable group of people in the following areas.

Evidence-based, cost-effective, yada, yada. Here is what we now know in terms of the availability of these kinds of analyses. You get to what Muin said in terms of you've got some efforts that are already pulling this together.

However, they are, in our opinion, inadequate, or need to be bolstered or supported by some other new things that people will have to have available to them. What we are saying to the Secretary is you've got a bunch of federal agencies, NIH, FDA, AHRQ, CDC, you've got all these people, and you control access to the kinds of data, or you should be creating the kinds of databases that allow reasonable and prudent people to make intelligent decisions.

We have really got to alert you, sir, that we need this research infrastructure, this information infrastructure, available right now. That means you've got to bolster this. Otherwise, CMS is in trouble, as is everybody else out here in the world.

MS. MASNY: I just also wanted to bring up comments that were made at some of our past meetings from the FDA or ex officios from the FDA and the FTC, that if there were guidelines like this, that they had actually requested that these guidelines then could be shared with their respective departments. That would also help provide guidance in their oversight of some of these tests.

DR. ROLLINS: Something else that Reed had just mentioned, which I just wanted to add to, also. When looking at a screening or a diagnostic test, those tests should be done if based on the results of it, there is something that you can do with it. If there are diagnostic tests available and they might show a certain something being present or absent, but if you can't do anything about it in terms of patient management, which would result in a better outcome, it is probably not a good thing to do.

In adding to what it is that you said a few minutes ago, I think that we should also take into consideration what actionable action is going to result from those diagnostic tests.

DR. TUCKSON: Would you consider ? - and I think the essence of this section as I read the report is would you consider a counseling intervention, Huntington's, would you consider that counseling opportunity a specific intervention that would then make that activity worthy of your analysis?

DR. ROLLINS: Yes, yes.

DR. TUCKSON: Let me just for the sake of argument. Would you consider in utero information about the sex of your baby, you know, or the color of their eyes, would you consider that information worthy of your analysis?

DR. ROLLINS: No.

DR. TUCKSON: Suzanne's asking what makes the distinction, and that's the point. What is the guidance? Or is part of the recommendation here how do we make some sense of what are the guidances here? Should the American people pick up the tab for everything possible that a person would want to know who is getting public insurance? Or should it be limited to certain things?

I think that's the other half of this whole recommendation. How do you help people to think through? So Part A is you've got the information. Part B is how do you help decisionmakers to think through what is a reasonable use of that information.

DR. LEONARD: I'm really disturbed by the argument that if there isn't anything you can do, then it is not worthwhile doing the test. I know from a personal perspective, if there is something wrong with me and there can be a diagnostic test that says it is either X or Y, and there is nothing that can be done, I want to know whether it is X or Y.

I want to know what my diagnosis is. I think from a physician perspective also, if you have a definitive diagnosis, you stop looking, you don't do other tests. There is utility in diagnosis, even when there is no therapeutic intervention.

DR. TUCKSON: So we go back to the ? - just to be provocative for a minute. What I think makes sense from what I hear is if you knew you had a diagnosis that would affect your reproductive decisionmaking, or at least inform it, that might be useful. If you had information that would affect the way in which you related to environmental toxins or personal health behaviors that you could actually change your health behavior, that might be important.

If you just, again, to know something about the color or sex of your baby, would that be enough reason to know? Or is it somewhere in between?

DR. LEONARD: I don't think color of eyes or sex of an infant is considered a disease. So I think the distinction there is that is a personal characteristic, if you will. I mean, you get into gray zones where there are characteristics that are sometimes considered personal characteristics, like obesity and things like that. Although one could argue that obesity is the most prevalent disease in the United States. But I think color of skin, color of eyes, sex of the infant, none of those would be defined as a disease.

DR. WINN-DEEN: I just wanted to remind people that this is in the section that is not just on public insurance. It is in the section that is on sort of all insurers. So we do need to consider that there is also each insurance company in collaboration with their customer, which is typically an employer buying a benefits package.

They can buy a benefit package that includes some tests, and doesn't. At some point in the future, employers might want to offer, you know, the blue-eyed, brown-eyed gene test for, you know, fetuses. God knows why, but if they chose to offer that as a benefit, as long as it was accurate and valid, they would have that right to do that.

So we should be, you know, there is a difference in what we pay for with public money, and what somebody elects to do on a private money basis. So we just need to keep that in mind, too, in where we put these different kinds of statements in the body of the document.

MR. DANNENFELSER: Yes, I think there is a question. I guess I had a question where it says "clinical" there at the bottom. Is that synonymous with therapeutic? I guess based on the dialogue that Reed had

there, I gather that that is what is meant there, clinical versus informational benefit.

I guess just in general, I think this is a real touchy area when you get into the area of whether it is therapeutic. Is it therapeutic to the infant and so on. I don't know that you are necessarily going to have a situation where the government is going to recommend something to private insurers that it is not going to pay for itself. That would seem to be not in synch for the government to do that.

MS. ZELLMER: I also would just point out, there may not be any immediate utility to carrier testing, but I don't think that is something that we should discourage coverage of carrier testing.

MS. HARRISON: I think likewise, if we go with the Huntington's example, you can't do anything about Huntington's now. I think you'd argue it doesn't have much therapeutic utility in the sense of before you acquire symptoms, there is not too much that can be done.

Yet I wouldn't necessarily ? - that's just informational for personal use. I think that is the whole purpose of a group like this who could make those distinctions, you know, of Huntington's versus the sex of the child, which, kind of just depending on what your arguments are, could put you one way or the other on them. I think that is the purpose of a group like this, and not for us to be trying to flesh out what is appropriate and what is not.

MR. MARGUS: It's only going to get more complicated. The other thing is we're talking kind of with the assumption that a genetic test is going to be an on/off answer. If we are talking about multi-genetic traits where the answer is going to be that you have a 64 percent risk instead of a 30 percent risk, now you're saying it is going to get even more complicated where people are going to wonder what the utility is of knowing it. This whole area is going to get messier and messier, as far as if you are holding it to a standard of it is definitely actionable or not.

MS. MASNY: It is not only going to get messier, it already is. I know in the oncology arena, we have already been faced with calls from people where genetic tests aren't being made available to the public. One was the case for ovarian cancer where they were looking at a panel of proteomic markers, and luckily the FDA stepped in, and at least the criteria there was that there was not enough validity studies that were done yet that could conclusively say that yes, this test is ready to be provided as a screening tool.

So I think that some of these general principles that we're trying to come up with, even if we have things like that, how many validation studies are necessary to show the effectiveness of the tests that could then move it into the public realm.

Secondly, just recently as a test for looking at modifier genes that will be used for the general public. Not just for high risk, but for the general public to determine what members of the general public will be at risk for breast cancer. So they are already out there.

DR. TUCKSON: Brad's comment is actually terrific, as well as Agnes'. I'm just starting to wonder. Obviously we cannot solve this. I'm just sort of thinking in my mind, what needs to be different a year from today so that we're not sitting at the same table going, oh my gosh, somebody ought to do something about making this make sense.

I guess it would be, at least in my mind, I would love to frame the issue even tighter that says here are the set of conundrums that are before the country in this area. This is why this is new, and this is what the paragraph I think tries to do. It says that there is something new about these genetic tests that introduce a new level of uncertainty and complexity that is different than before.

As a result of that, there are the following kinds of decisions that have to be made. They involve these categories of issues. The current organization of knowledge that solves those problems is comprised of the following groups. They are inadequate. As a result, there needs to be something else immediately put in place that permits this work to go forward in an organized way.

I guess that is what I'm not sure about. I think what we ought to be calling for here is the body of people, the right agency that it needs to be located in to make sure that we're not here a year from now having gone nowhere. I think that is what this recommendation ultimately is trying to say.

Maybe not being so prescriptive about what the group does, as much as ? - well, we need to be prescriptive. I guess I can't take it any further than that. Is there anybody in government today that is charged with thinking these issues through for the government? I mean, who is in charge of this? So when Brad says it is 60, what happens when it tests at 64 percent versus 20? I mean, who thinks about this?

DR. KHOURY: Part of the problem here, Reed, is that the efforts are fragmented throughout our sister agencies here. I mean, we all have a piece of the elephant. That whole elephant needs to be constructed in a way that the whole is bigger than the sum of the parts.

I think, you know, coming back to, was it you or Ed that mentioned about this HHS-level czar or czarina to try to put it together. You know, we have fragmentation.

That's enough from my side, I guess.

MS. BERRY: And Reed, do you feel that it should be one agency or governmental entity? Or does the group think that perhaps we might consider some sort of task force or commission that has the relevant agencies involved, but also the experts from the private insurance world and other stakeholders?

DR. TUCKSON: Boy, it's a great question. I'm really influenced by what Muin has said. That is that it sounds like this needs to be at a minimum across HHS. I'm not sure, I'd have to think some more about whether or not I ought to invite private sector people to it or not.

DR. McCABE: I was really quoting our esteemed leader when I brought that up before, who had made the comment in the past. I think Hunt Willard might be in a position to comment on this, because he has taken a position of leadership in a university where genetics and genomics used to be a department, and now has been elevated to a higher leadership role at Duke University.

I don't know if you could comment on whether that is for purposes of integration across the university. I think that's the kind of thing. We're looking for integration of genetics across HHS, and perhaps Duke is a model.

DR. WILLARD: Well, I rarely conclude that academia is a good model for government to follow. The argument that there needs to be an integrating body, whether it is a person or a body, is a different question. I think that is a recommendation this group may take very seriously. This isn't, as our mantra at Duke is, this is not just science anymore. This is science and policy together. So you can't point to any one of the HHS entities specifically and say, you're the one who should be in charge. They are the ones who should be in charge of some part of that pie, but then there is no one actually watching the entire pie.

So it is a reasonable recommendation for us to debate. Although I personally always hesitate to recommend yet another level of bureaucracy above the existing levels of bureaucracy. In this case, a coordinating body or a coordinating office, maybe there is something to be said for that.

DR. GUTMAN: Yes, I wanted to speak to Muin's comment, which is that it is a very colorful mosaic of regulatory controls in place that actually are driven by very different statutory bases and very different cultures.

You actually have as a baseline a very broad coverage by the CLIA program, which looks at the analytical validity and the underlying quality system in place. You have FDA for the products we review, which looks at analytical and clinical performance, at least in terms of a surrogate outcome on a device-by-device-specific basis. Then you get CMS, Aetna, or Blue Cross/Blue Shield, or Kaiser and whoever else, to actually pay for the damned thing.

In that case, they actually ? - I don't know that they will all uniformly follow Dr. Rollins' suggestion that before ordering a test, you decide what you'll do if it is positive, and what you'll do if it is negative. If you do the same thing, don't order the test. If you don't know, find out before you order the test. I don't know who does that or who doesn't do that.

I do think when the rubber hits the road, and when CMS makes payment decisions, and I presume the same is true for Blue Cross/Blue Shield, Aetna, Kaiser, and others, that there is the introduction of some kind of cost-effectiveness determination, or some kind of utility determination, even if you don't actually know the utility, which perhaps transcends both CLIA and FDA.

DR. GUTTMACHER: Yes, I think this is in some way sort of a multivariate analysis, and therefore, very difficult. It also brings to me the question of sort of genetic exceptionalism in a strange new application, perhaps. That is obviously I think everyone who would be against coordination, I mean, are the same people who are against motherhood and apple pie, I suppose. But besides that, coordination makes a lot of sense.

The question is if you tightly coordinate, first of all, the questions would be sort of regulations and laws that would allow you to do that are questionable. But also if we go back to the infectious disease analogy, we certainly don't have a czar or czarina of infectious disease within the federal government.

Now, maybe you would argue that we'd be better off for that, looking at recent problems with immunization, but I'm not sure that we would be in some ways having a multitude of different folks coming at this from different perspectives, even within the federal government, is a good idea.

Coordination obviously would be a good idea. We want to favor that. But the question is how do we favor coordination within what is sort of allowed. There is some difficulty in creating completely different ways of dealing with things which "are genetic or genomic" versus everything else, whether it be in science, medicine, or whatever.

Then there is also I think the question of are you going to coordinate things without making monolithic kinds of things. So it is a difficult kind of juggling act.

DR. TUCKSON: Well, we have a lot on the table here. First, I think one good model for how everybody benefits from what government does, and public resources and services to the nation, is the U.S. Preventive Services Task Force.

Now, here is a place where, again, I know everybody understands what that is. But to make sure that we have the best scientists that we can find in prevention, you know, who look at the literature carefully and thoughtfully, analyze that in a publicly transparent way, and make very specific recommendations.

Then those recommendations are available for people outside of government to benefit from and make

decisions based upon it. It is a terrific public service, and it is a good use of tax dollars, in my opinion.

So if you take that idea and you say here is a special new area of concern, I would sort of be saying, I don't think, Alan, that we need to necessarily create another bureaucracy. Maybe it is that we ask the government to bring its best thinkers together for a task. The task is we identify that there is a challenge that needs organized thinking across CLIA, AHRQ, and CDC. The task is that there are some specific questions around this new technology, these new interventions, that are different, and therefore require some thoughtfulness.

We want you to use the federal resources to bring it together transparently, and then make that information available for CMS and others to be able to take advantage of. We define it very specifically in terms of the range of issues we want, let the government figure out how to pull those people together. Don't create another bureaucracy.

When they finish their task, they all go home, and if they need to revisit it at some period, refresh it periodically, that's for them to decide. But then everybody has the benefit of it. That is one idea for you to shoot at as a way to go.

DR. KHOURY: Yes, I think this is kind of the model that we've adopted with the EGAPP initiative. We've had a lot of discussion with AHRQ before we launched the EGAPP initiative. The U.S. Preventive Services Task Force is the gold standard.

The problem, as Linda Bradley presented yesterday, is that the U.S. Preventive Services Task Force focuses a lot on clinical utility and the primary care setting. If you were to do an analysis of most genetic tests using the strict criteria of the U.S. Preventive Services Task Force, most of them will not meet that threshold.

As you said earlier, Reed, this is a complex new arena. We hear about that information for the sake of information, i.e., clinical validity, like you have a diagnostic test. It could have clinical utility built in by knowledge of your diagnosis, because it can avoid diagnostic odysseys. But then you bring in the ethic and legal issues, and then you have an ACCE elephant sitting in the room.

DR. TUCKSON: Muin, let me just make sure. I don't want to monopolize this. I want just for clarity sake, you are absolutely right. I do not raise the U.S. Preventive Services Task Force for any other reason other than their social role.

DR. KHOURY: Right.

DR. TUCKSON: Of organizing best thinking through use of public resources and making available to inform what government does in those outside of government in the interest of the nation. By definition almost, what this task is is the antithesis in terms of the methodology.

The U.S. Preventive Services Task Force, if it doesn't have 18 bazillion articles, they don't rule. So this is almost the antithesis in the sense that this would be going to unchartered waters, whereas the U.S. Preventive Services Task Force only goes in well-navigated waters.

DR. KHOURY: Can I take on another issue? The issue of genetic exceptionalism. I guess also Linda presented on this yesterday. I would agree with you, Alan, that there is no need for an infectious disease czar in the 21st Century.

But imagine infectious disease at the beginning of the 20th Century, or the 19th Century, where the

technology was still new. This is what we're facing with genetics. I mean, I don't know historically whether any one of the HHS was charged with controlling infectious diseases in the country, but I think the CDC comes as close to one agency that was tasked with ? - actually, its name was Communicable Disease Center back in the '40s or '50s when it was created.

So I think the model really applies only to the extent that you just have to subtract 100 years. If you look at genetics 100 years from now, then there is no need for that kind of coordination.

On the other hand, I agree with you. I don't think we should treat genetic tests in such an exceptional way per se, but the issues of the magnitude and the complexity of these tests deserve a look. Otherwise, we won't have all these advisory committees that have been formed, from SACGT up to SACGHS. There is a special one on newborn screening.

The government and the private sector have decided that genetics is worthy of a special look. I think the principles that we're talking about as we move forward in the practice of 21st Century medicine or genomic medicine, that will be integrated and can really have a long way in terms of influence on the practice of medicine in general, whether or not it is genomic or not.

I agree with you. In the long run, we want to have genomics as an integral part of the practice of medicine. But how to get there is sort of the challenge that we have right now.

DR. WINN-DEEN: I sort of want to agree with Muin, but go a step further. I think the issue is really what do you do with emerging new markers? I think it is broader than just genetics, except that genetics is probably the vast majority of emerging new markers.

Anytime there is a new candidate marker for something, you go through this process of gathering evidence that this marker actually has some usefulness. At some point in time, we need a group that gets together and says, okay, we agree that this is ready, and it should be adopted. I think that is part of the thing that is behind this recommendation is how do we get there, and the fact that a lot of these new markers are going to be in genetics just gives us sort of an opportunity to put a group with some special expertise in genetics together to do this.

But I think we're sort of talking around this and not really getting to the point of making a recommendation. I personally think the recommendation is not too bad, except that I would take and change the word "could" to "should." "The Secretary should task an appropriate group to develop a set of principles for coverage decisionmaking for genetic tests." That would apply to both employers doing private insurance and to public health insurance.

I also think that that group needs to have representation, and not just from people in the government. If it is going to develop recommendations that would apply to all, that you have to build consensus that everyone would agree that when this group makes a recommendation, that everybody is going to buy into it. You can't get that unless you have the stakeholders from the private sector involved as well.

MS. BERRY: Emily, are you talking about, and are we as a group talking about the group specifying when a specific technology or service should be covered? Or would it take a step back and be a little bit more vague or broad and establish principles and say these are the principles that we think everybody should apply, and then in going through that process, they'll make their own individual determinations as to whether they will cover something or not?

DR. WINN-DEEN: Well, I think to establish a set of principles is a good and useful task for everyone. I think SACGT tried to do that, and they went through a whole big algorithm of when do you know that

something has reached the clinical utility threshold.

There is still a lot of gray zone there. A lot of medical specialty groups have sort of stepped up and said, we're going to make a recommendation within our disease area specialty that this test is ready, and it should be applied in the following ways.

So it is a very fragmented thing right now. The question is just should we as a group make a recommendation that the Secretary of HHS somehow centralize this function and create a group that at minimum creates a set of principles, which then could be used, and potentially if you read the whole recommendation here, it goes farther, and actually says okay, and of the tests we know today, here are the ones that are definitely not on the list, here are the ones that are definitely on the list, and here are the things that are, well, basically everything else is still in the gray zone.

It either hasn't been evaluated yet, or there is not enough body of evidence, or whatever, to put it in one bin or the other. But that's the only way you're going to get to being able to make good coverage decisions and have some kind of unified coverage of new tests.

At some point they cross the threshold where just some people are covered into we really believe this is medically useful, and all carriers, public and private, should be paying for it.

MS. BERRY: To kind of tie this up, I guess is it safe to say that the group feels that there is something special about genetics and genomics that sort of cries out for some entity trying to provide guidance to either the public sector or the private sector and others? I mean, that is sort of the first question. Do we feel that there really is a need for this guidance?

DR. McCABE: Yes, I would argue there is a need for guidance. I would argue that there is not a special need for the guidance, but we aren't tasked with developing guidance for infectious diseases. We are tasked with developing guidance for genetics. So that is what we do. But I would argue it is not special, but there is a need.

MS. BERRY: Then what would be the most appropriate body to address that need? Would it be HHS and leave it vague? Would it be convening a task force that includes public and private sector stakeholders? Would it be a particular agency? Do we want to recommend the body, or do we keep it as is where it says HHS will convene this group, and we don't specify any other details?

DR. McCABE: In the original, it says that "HHS will task a group," and I actually prefer that language than "establish a group." In fact, the groups may already be established.

I would also maybe even make it vague and task group(s) with the "s" in parentheses, because there may be a need for more than one kind of a group, as we've heard from ACCE and EGAPP. It may not be a one size fits all.

DR. TUCKSON: I would agree with Ed, in that if I understand his point, first is that it is tasked instead of established. Therefore, it doesn't look like you are creating a whole series of reexisting bureaucracy that has a life of its own, which I think is something that we ought to be completely transparent about.

Number two, we want to be very specific about what the problem is that we want to get solved, but leave it to HHS to figure out how to best do it. Because as we've heard from Alan, Steven, and Muin, we can't possibly try to figure out all the machinations of the doggone government. That is only the things that they can figure out how to best use their resources, and who ought to be the charge of it and so forth. If those are the points that Ed is making, I endorse those.

MS. BERRY: Then to take it to the next layer, we think there should be guidance. We need guidance. There should be a group tasked with producing that guidance. Leave it to HHS to come up with the appropriate group or groups to do that work. Then the next layer is what is that work?

If it is establishing a set of principles and general guidance, that is a group then that could do the job and then fold their tents and go home. If it is to do that plus analyze specific technologies and be in existence and perpetuity as new technologies and services come into existence, there is some entity there that passes judgment on them, that's a different story. That sort of points us in the direction of an entity that has to continue to exist.

DR. TUCKSON: What if we were to give them the opportunity as part of their charge to determine what, if anything, needs to be done after they have, you know, done their work. Maybe make them make the recommendation back, instead of us trying to predict whether or not ? - because I think at this point we don't have enough information. To put it to their charge to make them determine what is the most appropriate course of action, and make that recommendation back to the Secretary, and to us.

DR. LEONARD: Well, it is one thing to develop the general principles that could then be applied to tests X, Y, and Z, or medical conditions X, Y, and Z. We have a whole bunch of recommendations to provide the evidence base to Medicaid, Medicare, and I don't think those are going to be communicated as general principles. So it has to be done on a test-by-test, disease-by-disease basis, so that the programs can actually change what they're doing, what they're covering, and what they're reimbursing.

So I don't know whether this group would do that, but I would see a series of recommendations. One where you establish a group to do the principles, but then those principles have to be applied to create the evidence base, and then that evidence base is what is distributed to all the people who need to know that information.

DR. KHOURY: One of the things we learned in the ACCE project is that you are dealing with a lot of apples and oranges, and we have only done five systematic reviews from prenatal testing, carrier testing for CF, all the way to BRCA1 and hemochromatosis.

At the end of the day, I have to agree that a general set of principles will not be sufficient. As a matter of fact, it won't be difficult to come up with this set of principles given all the work that the previous committees have done. The application of these general principles to a test-by-test basis is going to be complicated.

It is not only a test-by-test basis, but by intended use. You can use the same test for either carrier testing, symptomatic, or presymptomatic. Then all the parameters will change in terms of validity and utility, and then some of the ethical issues.

So I think if we have the U.S. Preventive Services Task Force as a gold standard for how those things are done with evidence-based principles in mind, then we shouldn't short, I mean, we shouldn't sell this very short. I think each one of these test evaluations is going to involve a synthesis and integration of the available literature, both published and unpublished.

These things are not cheap. I mean, it may take sometimes six months to a year to evaluate systematically what is going on with a specific test. I mean, for me, it is not rocket science to figure out that whatever you task HHS to do will have to go beyond coming up with a set of principles, but developing the approach and methodology for how these principles can be applied to specific situations.

MS. BERRY: Well, I've gone ahead and fast forwarded to the evidence-based recommendation. We'll go

back to the others. I wanted to pose the question to the group, should this be woven into the earlier recommendations so that we task some sort of entity, HHS tasks an entity to come up with a set of principles. That provides the general guidance. But then as Muin just mentioned, and Debra, there may be a need to go further on a technology or test-by-test basis.

That is what this recommendation gets to, which is assessing the actual evidence for specific test and technology. This group would also be charged with that task as well. Do we want to have a two-part component to the charge for this group?

DR. LEONARD: I would argue that there is no one group that could do all the tests. So I think for each test, you may have to have a different group with different expertise, I don't know. Once you have the principles, I think there is another gap, which is how do you determine which tests to do this for?

Are they the one with the greatest public health impact? Is it the one with the greatest penetrance in the population? Is it the one with therapies? I mean, how do you generate ? - that would be a very complex process, because you're going to do these one at a time.
It will take time to do that.

DR. KHOURY: You know, I wish AHRQ was here, so I'm speaking on their behalf. Forgive me on the webcast. One of the principles of the U.S. Preventive Services Task Force is that you have this independent body of 10 to 15 people that meets three or four times a year. They can decide, people can come to them and say okay, let's review this evidence for whatever it is. Whether aspirin prevents heart attacks, or whatever the issue is.

Then they deliberate. They are independent, and then the Commission in an evidence-based center, and there are many of these centers around the country. Obviously people who are specialists in cystic fibrosis may not be the same as in BRCA1. Then they do the evidence-based analysis and they bring it back to the table.

The task force, what they do is they look at the evidence, and they make the pronouncements up or down, quality and quantity of the evidence. I guess the experiment we're doing with EGAPP is sort of a collaboration with AHRQ to define the methodology, and then simulate that principle of an intendant body that these were the stakeholders, and then commission the systematic reviews, bring them back to the table, and then make some kind of pronouncement.

Then more importantly, because I think we feel that this is an area where a lot of research will have to be done, is identify very specifically the gaps in our knowledge then that can be funded through both the private and the public sector. So that a year down the road, there will be a change in the recommendation, or at least a statement about what we know about the genetic tests.

We won't get stuck for years and years saying that this test is no good. But next year maybe we'll come back and reevaluate it based on new data. So I think this is a moving target in a lot of ways.

DR. LEONARD: Muin, how do you see what we're proposing here as different from EGAPP, and should we just support EGAPP and ask the Secretary to give that resources?

DR. KHOURY: No, I don't think you should endorse specific activity. You should ask the Secretary to get the agencies to get their act together and see who is doing what, and let us collaborate. Because there may be another prescription to do this. I cannot presume that CDC has the only valid way of doing this. I think it is better for you to stay over maybe 10,000 feet, rather than go down on the ground with us.

But by convening, by asking for it, then the Secretary can poll the agencies and get them together and say okay, who is doing what, and let's figure out how to do it best.

DR. TUCKSON: As I'm listening to Debra and Muin, I am getting more and more convinced and confident that, you know, we have assessed that there is a problem. Here is the problem. We have assessed that certain things are going on, but they are not adequate. Therefore, this needs to occur. You need to make this happen. We want this done by a certain time period. It needs to be done.
I think that is really what it keeps coming down to.

But James, I wonder on Number 1, let's just say for you guys. Don't you do this?

DR. ROLLINS: Yes.

DR. TUCKSON: And I guess the question ultimately becomes, that is what you do? It is what is lacking? Or what don't you have that would make your job be more effective in this new area than you have today?

DR. ROLLINS: Yes. Everything that is mentioned in Number 1 is currently what we do when we do assess a new technology, be it some procedure, be it a new surgical technique, or even a laboratory test. So those are the processes by which we establish something that has shown sufficient evidence or has not shown sufficient evidence.

DR. TUCKSON: So the question it comes back to is can we articulate, and I'm back to where Debra was on this, I think. Can we articulate the set of issues that are of concern? The set of things that require new principles. The set of conundrums that are unique to this genetic era. Can we define with greater specificity the confusions brought by predictive tests that may not have clear clinical correlates?

Can we define with precision the cost-effectiveness decisions around introducing new technology when in fact there may not have been any preexisting method of intervention before with which to compare whether this is more cost-effective, too. If that is even English.

So I guess what I'm wondering is if we can sort of start to figure out what would be that list of concerns, and then frame those back and say here is what we're talking about as the range of issues that we think that this group needs to look at, and that you, Jim, and your agency, would benefit from having that information pulled together so that you can in fact through your existing processes make the decisions that you need to make, and such that information can be made available to the public transparently for others to take advantage of it.

DR. ROLLINS: I was getting ready to say, some of the things that you requested, such as cost-effectiveness and things on that order, that is something that we have actually not been charged to do. But I'm sure that information can be derived from some other source which could be used to supplement decisions.

But in terms of some of the other things which you've recommended, I do think that based on what it is that we currently provide, that additional information can supplement us in terms of providing additional information, or providing additional information for other uses.

MS. BERRY: We have to keep in mind as well though that we are also talking about private plans. Some plans have very, as identified in the report, very elaborate guidelines and processes that they go through, and have been willing to share that publicly when they make these determinations. Others may not be so transparent.

So to the extent it may be that CMS has this process in place, but maybe in the private sector it doesn't exist, or some do and some don't. So there may be some value in having someone outline that so that the general public will be aware of what goes into a coverage decisionmaking decision, and it is not just some hole that, you know, the request is in and no one really knows how the decision is actually reached.

DR. WILLARD: I'm afraid we have to do a somewhat better job of articulating what the problem is. I think we probably all somewhere in our guts think that there is a problem.

If I just heard from Dr. Rollins that CMS is doing Number 1, then I either need to hear that CMS isn't happy with the job that they're doing, or that someone else isn't happy with the job they're doing in order for me to feel comfortable to say okay, now we've identified a gap. We either need more information provided to help CMS, or more information to have them come up with a different answer than they might have come up with.

That same question could be asked over and over again, whether it is for the CDC or any of the other groups that are within the federal government, or under HHS. My concern is we just are not drilling down to a very concise statement of what the issues are, other than there is uniform angst. I think we probably need more than that.

MS. BERRY: Dr. Rollins, I know that CMS undertakes this type of process in Number 1 for all medical services and technologies. Would you say that your ability to undertake that process in the area of genetics is hampered in any way because of a lack of evidence? Or do you feel that CMS has what it needs to proceed with that process in this area?

DR. ROLLINS: I think that CMS is capable of pursuing any request pertaining to the effectiveness of genetic tests. So I do think that as long as there is information out there available to assess, we are in a position to make those decisions.

MS. BERRY: Well, then Hunt goes back to the original threshold question which we raised, which was is there a uniform feeling that guidance is needed, that there is some issue, problem, or deficiency, in the fields of genetics and genomics that cries out for some sort of guidance by a federal body or federally tasked or charged body?

DR. ROLLINS: I'll make a quick comment. When looking at a technology, not only with CMS, but also the commercial plans in terms of coverage decisions, they base their decision on the effectiveness of that particular technology.

If there are other questions which go beyond that, such as cost-effectiveness, or certain types of utility, that is something that is beyond what it is that we look at. We essentially look at the literature in terms of determining whether or not a test is effective or not effective.

So any additional questions beyond that might be something else that might, you know, we may not address, or other plans may not address. For that reason, additional information may be needed, or additional direction might be needed to address those additional questions.

MS. MASNY: I just have a question for you, Dr. Rollins. If a test though was deemed to be, a screening test then would not be covered by Medicare or Medicaid. Would then CMS undertake this type of assessment?

DR. ROLLINS: We do cover diagnostic services, as we discussed yesterday, in terms of screening

diagnostic services. That is something that has not been required, it is something that has not been mandated by the government for us to do. As I say, diagnostic tests, yes.

DR. WILLARD: You know, in essence, the issue comes down, and I'm not sure whether we can do it, that either we have to, or we need to charge or recommend to the Secretary of HHS that he attempt to do what the Supreme Court refused to do for pornography decades ago, which is to try to define exactly where the gray zone is, which is almost oxymoronic. By definition, you can't do it.

I mean, we all agreed going around the table that testing for Huntington's disease in certain settings had value. It was effective at some level. But testing for blue eyes or brown eyes was not going to be of value, or not viewed to be effective, and therefore wouldn't be.

So those are polar, but the area in the middle, unless we feel we can bring something new to the table, or that some other group is going to bring something new to the table to define better the gray zone, I'm not comfortable that we have much to add to the dialogue, except acknowledging that there is a gray zone, and it is going to take great care and thoughtfulness on many people's part to continue to evaluate this over time.

MS. BERRY: Remember, we were talking about two different parts to the charge. The first was a set of principles which would look at issues such as the informational utility, medical effectiveness, the preventive nature of genetic services, and have these general principles developed so that they could serve as a guide both in the public and the private sectors.

The second part was more the test-by-test, technology-by-technology assessment based on the evidence. It sounds like that second part may not be a problem. CMS feels that it does that, and can do that. There is a question about whether the private sector uniformly does that, or whether there is some need for guidance there.

But if we're going back to the beginning, Hunt, to you suggesting that even the first part of the charge that we talked about where we would have some group establish a set of principles, that maybe that isn't clearly necessary.

DR. WILLARD: I'm certainly open to the possibility that a group could come up with a set of principles that would say, this is what we mean by the 5 prime N, and these ones are clearly at the 3 prime N, and then there is all this stuff in the middle that we can't really declare.

I mean, if we felt that there was a group that could provide sufficiently robust and specific guidance on what is at the left and what is at the right, then there would be some value to that. But if it is simply to discuss year after year, as Reed was alluding to previously, everyone saying boy, there are some things on the left, there are some things on the right, and there is a whole lot in the middle, then I'm not sure if it is worth either the recommendation or the dollars that would flow therefrom to pull that group together.

MR. MARGUS: My suggestion was maybe if we're concerned about tests that might not be covered, and particularly with CMS, just to clarify what Dr. Rollins said. If there is information available, then CMS reviews it and uses it.

So maybe we could in situations where information is available, that CMS would speak up about it, or that we would be that someone then fills in. What we're concerned about is when, and correct me if I'm wrong, is that we're concerned that in certain situations tests fall in La La Land and don't get covered because there hasn't been anyone building a case for it, and CMS is very open to reviewing information and using it if information for, you know, necessity or validity is there.

That's only when the information is there. If the information isn't there, what do you do? Maybe we should put that the recommendation would be if there are gaps to having that information, then something has to happen.

MS. BERRY: Well, and also, to go back to a point that was raised earlier, CMS wouldn't undertake the whole process like this to look at the evidence for a technology that it is statutorily prohibited from covering. So we can't completely rely on CMS' ability to be the final arbiter here.

They'll do what they can within the purview, within the scope of their authority, but then there are other payers and components of the health care system that do require some sort of process like this that can't just be CMS because they are not bound by the same statutory constraints.

DR. ROLLINS: I think that most payers, commercial as well as CMS, follow this same type of process. So in terms of evaluating the evidence, we are all pretty consistent. The only restriction is, as I say, because we do not cover screening tests, those are something that we would not review. Commercial insurers, they have the option of covering both diagnostic as well as screening tests. As I say, whether or not it is diagnostic or screening, they follow the same type of evidence-based review process.

DR. WINN-DEEN: Okay, so in the interest of moving this all along, pages 60 and 61, and then this whole box that we're discussing on page 69 are repetitive, and we should get that organized in such a way that we don't say the same things twice, and don't have the recommendations on two separate pages.

It seems to me that what is lacking is not that there is a process that happens at CMS, or that there is a process that occurs at different private insurers, but what is lacking is sort of a publication of what that process is. So that people working in the field with emerging tests, many of which are these genetic tests that we're talking about, know exactly the questions that are going to be asked, so that data can be generated to address those questions.

So I would say that maybe one of the things we could ask the Secretary to do is to ask CMS to publish in some manner, if you don't already, that list of questions. What are the criteria that you use that you go through in the process? If you have a standardized process, what is it? Can it be transparent?

And then the second part, which is this whole issue of RFAs, is I think a way to address the issue of lack of evidence. A lot of things are in the gray zone because we just don't have enough information yet to say that they belong in a black or white category.

So I personally would like to advocate for continued NIH kind of RFA grant support to continue to generate information. Maybe it is CDC studies or whatever studies are required to get things to the point. We have enough evidence to say this is right, this isn't right.

I think that the hereditary hemochromatosis case study that is on the opposite page there is maybe a good example of that, where clearly you can test these mutations that they have some utility in clarifying a diagnosis in someone who is presenting with family history or signs and symptoms.

We don't yet have the body of evidence to say it is worthwhile doing a screening, population screening, and so we are doing a big study funded by the NIH to answer that question. So I just would like to sort of bring this to closure. I think the gap is that we need clarity on what the criteria are that generate coverage and reimbursement decisions, and then we need a way to fill the gaps for new things so that you can generate the evidence that's required to go through that process.

MS. GOODWIN: Actually, the Medicare Prescription Drug Act tasked the Secretary with making

available to the public the factors that are considered when making national coverage decisions. I believe CMS has taken the first steps in that process. So it is not available yet, but it is something that is being done at the moment.

DR. LEONARD: In addition to the preventive aspect that is not covered by CMS, I would also argue that what would be covered by Medicare with an over 65 population is very different, and may not be considered for the 5-year-old, the 20-year-old, and the 40-year-old. So I don't know that CMS' policy coverage decisions apply to the entire population that is going to benefit from genetic testing as opposed to being restricted to the elderly population.

DR. WINN-DEEN: I guess I just meant that there must be a list of questions that they go through, and that set of questions that they go through, aside from the fact that one of the questions may be is this a screening test, yes or no, and if the answer is yes, it is off the table. I think that the list of questions in the process would be informative for most tests, probably.

DR. LEONARD: Except how much do you take into consideration with these decisions that you're talking about the over 65 population or the elderly population, as opposed to what would be good for a 20-year-old?

DR. ROLLINS: Well, I would respond and say that about 85 percent of the Medicare population are persons 65 and over, and like 14 percent for disabled persons. So it would apply to that group.

In terms of a process, CMS does currently have a process, and a person can actually go to the CMS website basically telling them how to initiate a process in terms of requesting a national coverage decision for a particular technology.

That information out there also would help in helping them to determine what type of information is necessary for that process to take place.

MS. HARRISON: I don't want to get us into another whole topic, but I was wondering, we have been talking a lot about testing, but we haven't really been talking about the accompanying services to testing, i.e., genetic counseling. How decisions are made about whether that is covered, or not, or even in whether a physician feels that he could bill for that or not, since we know genetic counselors can't.

I'm just wondering, would it be a similar process if someone was trying to pursue coverage for counseling?

DR. ROLLINS: I don't know, but I would think it would probably be a similar process.

MS. HARRISON: Okay. Well, just while I had the mike, the other list that we're working with where we read out some of the principles that that group should work with, I wanted to propose to stay with that, which I'm not sure if we're going to.

If we do stay with it, I thought maybe something to the effect that the principles should also address accompanying services necessary like genetic counseling or genetic evaluation to ensure quality care and recommendation of tests. Just to make sure that there are tests that can be available, but some tests should probably only be available if they are recommended by a genetics professional as opposed to a general physician, nurse, or something else.

DR. TUCKSON: Yes, actually in danger of violating my all comments must lead to conclusion statement, Emily, I'm glad you brought us back to this hemochromatosis case study. Can I just ask, does

anyone remember where the groups, the working groups, were they in government or out of government that created these conclusions? Does anybody know where that came from?

MS. MASNY: I know that there was a paper from the task force on hemochromatosis. So I think one of the aspects of this is from the United States Preventive Services Task Force.

DR. TUCKSON: This was a U.S. Preventive Services Task Force?

MS. MASNY: Yes.

DR. TUCKSON: I mean, if you look at this, Emily, I think it is really right to bring this out. Here is a great example. Here is a complicated issue that has a significant prevalence and penetration in society. There are a lot of people involved, you've got a test for it. The question is, do you offer this or not?

Then they make a very cogent sense of a clear evaluative process that ultimately concludes that under which conditions this is appropriate, and which conditions it is not appropriate. Having this kind of analysis available for decisionmaking is extremely important.

How do you organize yourselves to be able to create this kind of analysis on a test-by-test basis? But if this came out of government, I'm just wondering what the organization of government services are that made this happen.

MS. GOODWIN: Part of this case study was included based on a conversation at our previous meeting where I think you brought up this example. Are you familiar with the working groups?

PARTICIPANT: I'm sure I was at one point.

DR. WINN-DEEN: I have all the papers in my office. I can send you them.

DR. TUCKSON: No, I'm sorry. I just was trying to see whether or not this was a model of a way of proceeding. N James, is this the kind of information that if you all had available, you could make decisions?

DR. ROLLINS: I think that type of information would help supplement us in making a decision, yes.

DR. TUCKSON: Yes. The question is if you look at the genetic tests that are out there for you to have to make decisions about today, do you have a place to go to get this kind of data?

DR. ROLLINS: We review the peer review literature. We would also review any information available on some of our public websites, such as AHRQ. We sometimes communicate with various societies to get a perspective on the utility of the test.

DR. KHOURY: I guess I was out. Was a question specifically posed to me? Or shall I just jump in?

DR. WINN-DEEN: We just wanted to know what the background was on HH, if you remembered if that was all government, or if it was public/private.

DR. KHOURY: No, I mean with hemochromatosis, we've had a number of meetings, starting with one we held collaboratively with NHGRI back in 1997 to look at evidence for population screening.

The most recent activity is the ACCE report, which is a systematic review of the whole elements of

population screening. It looked at analytic validity, all the way to the ethical issues. That was put together by the Foundation for Blood Research in collaboration with people who are sort of the experts in hemochromatosis.

DR. TUCKSON: Muin, what I was trying to get to, and you may have answered it, is just simply a matter of this is in there as a case study. I was wondering, is this a case study of the way in which the system can work to organize data, information, and analysis, and then feed it back for decisionmaking for government and others so that you expedite the concerns that we had here? Is this a model that can work? Or does it really tell us that, I mean, the ranges of permutations and complications on any one of these. You can't create a freestanding body that is going to do it all the time, and that you basically just have to do it case by case the best you can.

DR. KHOURY: Right. I think this was brought to SACGT a couple of years ago as a case study for how government agencies work together. I think it is a good case study. Once the gene was found in 1996, two agencies came together and said okay, let's look at it. There were early calls for population screening.

However, having said that, I don't think, unless there is some kind of a situation where these things are anticipated, because there will be many, many hemochromatosis to come, pharmacogenomic tests, who is going to be keeping tabs on this? I think that is the issue. Is it a case-by-case basis, or something a bit more overarching?

MS. CARR: Well, what I was wondering about was if these are done in sort of an ad hoc way, how are the decisions made about what next issue to look at? Is that where some help is needed, that there be a body that would say okay, well now the next thing that we need to look at and evaluate through this sort of process is this test or this mutation?

Because otherwise, it is going to be decided I guess through specific people who are interested in that area. So I think that that is where the committee might consider some more systematic approach.

DR. KHOURY: Right now, there is no such process in place. It all depends on the sort of networking and the discussions that go on in the hallways and behind the scenes with the professional society.

Somebody might say, we have a test that we think is reasonable, but there is really no process that is established. We were hoping that the EGAPP would serve as a model for such a process. Maybe not the process itself, but over the next three years we can learn from it and see how it will work.

MS. BERRY: How about, just to try to wrap this up, to go back to the beginning. Is there a consensus that we do need some guidance in the area of genetics and genomics for public and private payers that would take the form of an entity or several groups tasked by HHS to establish a set of principles along these lines that would assist in making coverage determinations? That is sort of the threshold question. Is the problem of lack of guidance severe enough that it merits this group making a recommendation specifically to the Secretary setting up some sort of task force or entity?

DR. TUCKSON: I come back to the Huntington's point, Hunt's point. I'm just not sure that we have defined enough the problem. I just don't see how we can make the recommendation today until we all at least have a feeling that we can rehearse on the same gospel hymn, the problem. I just don't know whether we all have in our mind what we are trying to solve. Maybe I'm the only one.

DR. LEONARD: Could we ask the agency representatives to provide input if they feel there is a gap, what that gap is, so that it could inform our discussion when we come back to this next time?

DR. KHOURY: I'd refer you to Linda's presentation yesterday. Maybe I can go over it again. I think the case can be made again and again that there is a big gap right now. It is a knowledge gap, it is a policy gap, it is a reimbursement gap, and all of these things go together.

The number of tests that are coming down on the market are not going away, they are only increasing. With all due respect with the CMS work they're doing, I mean, there is a screening exclusion, and they are mostly dealing with old people. So we have to develop something a bit more sustainable, and I think that pulls all the agencies together.

DR. TUCKSON: Can you define, and I hate to put you on the spot.

DR. KHOURY: No, that's okay.

DR. TUCKSON: But can you define it? I mean, can you just say in your mind, you know, the preamble would be, Dear Secretary, we have discovered this problem. It is, therefore, do this.

DR. KHOURY: Well, you know ? -

PARTICIPANT: With the understanding that you won't be saying that. We will be.

DR. KHOURY: Well, let me step back here. If we are trying to develop a robust process for evaluating genetic applications and practice, and what we have to do, I mean, you as a committee have taken a look at issues from discrimination to reimbursement, coverage, evidence-based, and criteria.

If you think that there is no problem, then we can all go home. At least what I said, I think that there is a major problem, because the number of genetic tests that are coming down the pike have no way to go but up. Each one of them, it defies our conventional wisdom of evaluating clinical utility in the traditional AHRQ or CMS model.

We are dealing with different parameters of information, ethical issues, and clinical validity, other than the medical way of looking at it. Thirdly, basically there is really no process right now in place that takes care of all these issues together. I mean, they are a fragmentation of efforts.

AHRQ has not up to this year, taken on any genetic tests for primary care. They tell me if we use them through the AHRQ U.S. Preventive Services Task Force model, they will all fail. Why they will all fail is because they have a clinical effect on us, and a traditional way of doing business that I'm sure the genetics community may want to modify to have a further look at this.

So there is coverage and reimbursement, and there is people calling for services. I mean, we heard from the consumers yesterday. So I can't reinvent the wheel. I thought that the wheel had already been invented.

DR. TUCKSON: So Muin, what it boils down to in terms of I hear you is we all understand the issue that there is lots of tests coming in. What you are saying is what is different is that we do not have a robust enough ability to evaluate the clinical utility of these new tests because there is something special about these new tests, i.e., they are predictive, and something else about them.

It has to do with, as you boil it down, the ability to evaluate clinical utility of a new kind of test. Do you want to augment that?

DR. KHOURY: No, I want to guard against genetic exceptionalism. So, I mean, I'm walking a very tight

balance here. It is not only about clinical utility, but evaluating the whole spectrum from the analytic validity to the ethical issues.

The traditional medical model is clinical utility for coverage of new technology. But with genetic testing, I think we have to take a look at the whole spectrum of data and information, knowing that there are actually lots of gaps in our knowledge. If we really want to move forward integrating genomics and medicine, I think we need to develop all these processes to get that done.

We have spent a lot of resources and billions of dollars to map and sequence a genome. If we can't go the next steps in trying to figure out how it can be used in actual practice, I think it would be really not a good outcome for our country.

DR. LEONARD: I think that with genetic testing, you are looking at an entire paradigm shift with the practice of medicine. In that you will have knowledge from testing one person that applies to an entire group of people, whoever is related to that person. With those other people instead of waiting for signs and symptoms to develop and then doing a diagnostic test and treating them, we will have the capability of potentially taking preventive strategies for those other family members, not having them wait until they have signs and symptoms.

So how you implement that is difficult. We are used to thinking of medical practice in terms of individuals and not in terms of families.

DR. TUCKSON: Let me just do this. Cindi has still got the helm here, but let's just do a reality check. We are at 12:30, we've got a guest at 1:00, and we've got to eat. We have a real cramped schedule here. I think we heard just now one person describe what the problem is. We've heard Debra, she took a shot at it, and we didn't give her a chance yet to get into the level of details. She is talking now there is really a paradigm shift. That paradigm shift can be defined, I'm sure, by a set of characteristics.
Cindi, let me just come back to timelines. This is really important work, and it is important to get this one right. I still think we've got some more drilling down to do, particularly in defining the problem, and then being able to have a cogent set of recommendations, just for this section, much less a couple of other sections.
Cindi, when, again, I can't remember, is there a drop dead date by which this committee committed that it would have this report out? Is there a reason that this report has to be out the door on a date certain?

MS. BERRY: In the timeline that staff has suggested, the due date for additional edits after this meeting would be October the 29th. In November, the staff would prepare the next draft and the Federal Register request for public comments. The public comment period would be generally December to January, and then the next SACGHS meeting, of course, is February 28th to March 1st, where we would review the public comments received at that time, and finalize recommendations.

DR. TUCKSON: Well, it seems to me that we would like to keep that, at least to the last date, which is the March 1, you know, getting it out the door and into March is a reasonable timeline. Now, I'm not sure, but what I think we will do is during the lunch period, I mean, clearly you as a committee are going to have to weigh in on some more of these issues. I don't think that the subcommittee itself can do it all without you being involved. There is discussion that has to occur beyond the time that we have available right now. So we are going to have to figure out whether or not that means, again, through a conference call, or whether it means that we push everything back and bring more work back to this committee. I mean, we're going to have to figure out a set of tactics here. But we can't resolve this issue right this second. I'm looking to you all for some guidance around how you want to move forward. We've got to decide this right now.

DR. TUCKSON: Well, let me ask Cindi as Chair of this group, what is your thinking is on behalf of your committee? That is this. The one thing we don't want to do as a committee is extend every doggone report 20 cycles, and we never issue anything of importance, and we just look like an ineffective group.

Do you feel though that this will need to move back one meeting cycle so that we can come back, revisit, and tighten down on these issues that are unresolved? Or should we go ahead and try to get some stuff, some work done between the subcommittee and the full committee between now and the next scheduled meeting? Should we try to go ahead and keep to our schedule and just try to get it done outside of a formal meeting room?

MS. BERRY: I think the issues that are remaining that we haven't yet gotten to here probably can be disposed of pretty quickly. I think we can stick to the original time frame. The big kahuna of course is this big issue that I don't have a sense that we can really go back and draft anything, because there really isn't a consensus yet. So it may require a conference call of the full committee to do. I think by doing that, we still can stick to the original ? -

DR. TUCKSON: Can I ask the full committee, Debra, and part of your response, I know you all work real hard on this committee. I'm loath to ask you to do extra work, but would you be willing if we could structure a very tightly framed call that was very clear about the issues to be discussed, would you be willing to participate in that between now and the next meeting?

DR. LEONARD: Yes. That's the short answer to your question. I think given our earlier discussions on the genetic counseling issue, the data gathering that is going to happen, and informed discussions at the next meeting, I don't see any way that staff can generate a report to go out for public comment before our next meeting and gather those public comments. So I see no choice but to move back by one cycle, unless Sarah says you can work miracles.

MS. CARR: I think the committee has raised a number of really significant questions. I think we felt, staff did, that coming into this that there would be more. I know that I am somewhat diverting from what Cindi just said. I think that this feeling I have is that you have raised some very fundamental questions that we need to gather more information for you about, and as Debra just said, a lot more information needs to be gathered about the counseling, the licensure issue, and so forth. So my inclination is to push it back one, even though I was raring to go and hoping this would be done by the next meeting.

DR. TUCKSON: Great. Cindi, would you accept the pushing it back?

MS. BERRY: Sure.

DR. TUCKSON: And then I think what we want to do is so that we don't lose the momentum, and we've got to really break off, I would urge the committee, Cindi, through staff -- Suzanne, Amanda, and everybody else -- let's try to get something back out to us right away that lays out where we are and what is uncertain so that while it is fresh in our minds, we can think about it. So that we don't lose the momentum of trying to drive this thing forward, let's start clarifying what really has to occur next. So we'll get that out to you right away.

Let me just close by saying to Cindi and the committee, you know, you've done us a great favor to get us this far. This is hard. So I don't think we should be disappointed. To the staff, you worked your tails off on this thing, and we really want to thank you for that. We're going to keep at it. We'll get it done in short order. (Recess.)